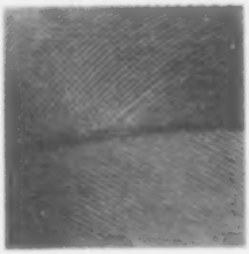
ABS

International Expert Workshop on Access to Genetic Resources and Benefit Sharing

Cuernavaca, México, October 24 - 27, 2004



Record of Discussion

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Environnement Canada
Agence canadienne de développement international
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Government of Canada
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Swiss Agency for the Environment, Forests and Landscape SAEFL

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Organized by

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Environment Canada
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Table of Contents

1. Co - chairs Reflections 13
2. Generating New Ideas and Thinking: Record of discussions 19
3. Overall Evaluation of the Workshop 47
4. Experts' Papers 51

Section I: Identification of Outstanding ABS Issues 53

A. Level of National Implementation 53

National Implementation, by Valérie Normand 55

B. National Access Laws (Challenges), Continuing Monitoring and Enforcement Issues 59

The Challenges in the Implementation of the Philippine ABS Regulations: Monitoring and Enforcement of Bioprospecting Activities, by Paz Benavidez II 61

National Access Laws: Challenges, Benefit-sharing, Monitoring and Enforcement, by Geoff Burton 66

Developing and Implementing ABS Regulations in the Pacific Rim Region: Issues and Challenges, by Santiago Carrizosa 74

Briefing Note: National Access Laws (challenges), Continuing Monitoring and Enforcement Issues, by Robert J.L. Lettington 79

Discussion Paper: Access Laws: Challenges in Implementation, Monitoring and Enforcement, by Manuel Ruiz 84

C. Access to Genetic Resources and Intellectual Property Rights: What is Biopiracy? 87

What is Biopiracy?, by Graham Dutfield 89

Discussion Paper: Access to Genetic Resources and Intellectual Property Rights: What is Biopiracy?, by Stephen Smith 93

Section II: Vision and Nature of an International Regime: Goals, Challenges, Gaps and the Role of the CBD and other Bodies 97

A. Vision and Nature of an International Regime 99

Vision and Nature of an International Regime on ABS, by François Pythoud 101

The International Regime from an Implementation Perspective: What Legislation Can (and Cannot) Do… and How this Affects the Vision and Nature of the Regime, by Tomme Rosanne Young 105

The International Regime, as it Applies to Plant Genetic Resources for Food and Agriculture (PGRFA), by Stephen Smith and Tom Jacob 112

Vision and Nature of an International Regime: Minimum Requirements and Options from a Practical Developing Country Perspective, by Robert J. L. Lettington 118

Discussion Paper: International Regime on ABS: Exploring New Options for Achieving CBD-related ABS Objectives, by Stanley S. Atsali 121

Discussion Paper: The International Regime – A Missing Element, by Geoff Burton 125

Discussion Paper: Nature of an International ABS Regime, by Jock Langford 127

Discussion Paper: Towards an International Regime that Stresses Infrastructural Capacity Development in the Source Countries as a Key Factor for Effective Access and Benefit-Sharing in Bioprospecting, by Augustine Bantar Njamnshi .. 130

Discussion Paper: A Few Thoughts on the International Regime and Provider/User Measures, by Nicola Notaro 134

Section III: Specific Issues for Consideration in the Elaboration of the International Regime **137**

A. Interface with Existing IP System & Limits and Opportunities for Existing IP Rights ***139***

Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications, by Martin A. Girsberger 141

The Interface with Existing Intellectual Property Systems: Limits and Opportunities for Existing Intellectual Property Rights, by Kim Connolly-Stone 147

Four Reforms for Wider Benefit-Sharing, by William Kingston 153

ABS and the Interface with Existing IP Systems: Limits and Opportunities, by Ruth Okediji 159

Discussion Paper: Pharmaceutical Industry Scenarios and Questions Relating to Patent Disclosure, by the European Federation of Pharmaceutical Industry Association (EFPIA) 165

Discussion Paper: Biodiversity-based Patent Term Extension: an Opportunity for Using the Existing IP System to Support ABS, by Jock Langford 168

Discussion Paper: Intellectual Property Issues: A revision of the current UPOV PVP is required to support the Conservation, Sustainable Development and Benefit-sharing Goals of the CBD, by Stephen Smith 170

Discussion Paper: EPRs and the International Regime on Access to Genetic Resources and Benefit-Sharing, by Jesús Vega 173

B. Limits to Rights Over Genetic Resources, the Issue of Derivatives: Defining the Line between Tangible and Intangible Property Rights 175

Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives, by Fernando Casas-Castañeda 177

Discussion Paper: A Plant Chemist's Perspective on the "Problem" of Derivatives, by Kelly Bannister 183

Discussion Paper: Derivatives, by Geoff Burton 185

C. New Forms of Sui Generis 189

Sui Generis Protection of Genetic Resources and Associated Traditional Knowledge, by Jock Langford 191

New Forms of *Sui Generis* Protection, by Graham Dutfield 196

Discussion Paper: New Forms of Sui Generis Protection Relevant for the International Regime (GR and/or TK), by Shakeel Bhatti 199

D. Indigenous Peoples: Community-level PIC for Accessing TK and Genetic Resources, Feasibility and Good Practices 207

Customary Law as the Basis for Prior Informed Consent of Local and Indigenous Communities, by Brendan Tobin 209

Indigenous and Local Communities: Community-level Prior Informed Consent for Accessing Traditional Knowledge and Genetic Resources, by Peigi Wilson 214

Discussion Paper: Lessons for ABS: Academic Policies Community Protocols and Community Level PIC, by Kelly Bannister 219

Discussion Paper: The Road to Effective Prior Informed Consent for Accessing the Traditional Knowledge and Genetic Resources of Indigenous and Local Communities in Colombia, by Gabriel Ricardo Nemogá Soto 222

E. Measures to Ensure Compliance with CBD and Access Legislation. Stakeholders, Scientists as Users and Providers, Codes of Conduct/Awareness *227*

Mechanisms for Compliance with ABS by the Academic Research Community (Canada), by Kelly Bannister 229

Scientists as Users and Providers: a South African Perspective, by Maureen Wolfson 235

Discussion Paper: Relevance of Genetic Resources to the Pharmaceutical Industry, by Susan Kling Finston 244

Discussion Paper: The Smithsonian Institution: the Life of Natural History Museum Specimens, by Leonard P. Hirsch and Ana Cristina Villegas 251

Discussion Paper: Access and Benefit-sharing: Role of Scientists, by Jock Langford 256

Discussion Paper: "Genetic Resources" and "Utilization of Genetic Resources": A Legislative View, by Tomme Rosanne Young 258

Section IV: Instruments/Tools/Measures which could assist in Achieving the International Regime including Mechanisms for Monitoring and/or Verification **263**

A. Certification systems: Product and Process Certification Including Certificate of Legal Provenance/Source/Origin *265*

Elements for the Design of a Certificate of Legal Provenance, by José Carlos Fernández 267

Certificates of Origin, Legal Provenance and Source: Mutually Exclusive or Complementary Elements of a Comprehensive Certification Scheme, by Brendan Tobin 271

Discussion Paper: Certificate of Origin/Source/Provenance, by Mariana Bellot 278

Discussion Paper: ABS Certificate System, by Jock Langford 279

Discussion Paper: Uses, Benefits, Tracking and Trade-offs: A Botanical Collections Perspective, by Kathryn Davis 281

Discussion Paper: A Simple Solution: Using Certificates of Legal Provenance as a Workable Component of a Functional Regime on ABS, by Tomme Rosanne Young 284

B. Certification Systems: Company Conduct, Standards and Certification *287*

ABS Management Tool Project: Summary Project Description, by Jorge Cabrera and George Greene 289

Tropical Biodiversity: an Industrial Perspective, by Lene Lange 296

Discussion Paper: Company Conduct, Standards and Certification, by Peigi Wilson . 301

C. *Measures and Compliance Mechanisms for Key Actors: Government User Measures – Incentives for Compliance* *303*

Government User Measures-Incentives for Compliance, by Birthe Ivars 305

User Measures in Provider Countries: Use of Simplified Procedures and its Trade Implications, by Christian López-Silva 309

D. *Benefit-sharing: Benefit-sharing as a Goal of the IR* *317*

Access to Genetic Resources and Benefit-Sharing, by Mohamad bin Osman 319

Benefit-Sharing as a Goal of the International Regime: Lessons Learned from Genetic Resources Research at Yellowstone National Park, by Preston Scott 324

Discussion Paper: Benefit-Sharing as Process, by Kelly Bannister 329

Discussion Paper: Benefit-Sharing, by Jock Langford 331

Annexes 333

Annex 1. Workshop Agenda 335

Annex 2. About the Panelists 339

Annex 3. List of Participants 347

Please note that all the papers are also available online at:

www.canmexworkshop.com

1. Co - Chairs Reflections

Co-chairs' Reflections[1]

Context

The Canada-Mexico International Workshop on Access and Benefit-sharing convened a broad range of experts in Cuernavaca, Mexico, October 24-27, 2004, to discuss a number of issues key to the negotiation, under the Convention on Biological Diversity (CBD), of the International Regime on Access and Benefit-sharing (ABS).

Participants, who were invited in their personal capacities as recognized experts in the field, gathered together in Cuernavaca representing academia, NGOs, scientific institutions, indigenous organizations, international organizations, industry, and governments from around the world.

The conception of the Workshop stemmed from an interest expressed, by a number of governmental and non-governmental representatives during the Seventh Meeting of the Conference of the Parties of the Convention on Biological Diversity (COP7) in Kuala Lumpur, Malaysia, in convening experts (outside formal negotiations) to advance thinking on the many critical and complex issues raised by the International ABS Regime. The Mexican Secretary of the Environment, Alberto Cárdenas, offered Mexico as the venue for such a workshop and prior to departing Kuala Lumpur, Canada and Mexico informally committed themselves to organizing just such an event during the Intersessional period between the COP and the Third Meeting of the Ad-hoc Open-ended Working Group on ABS scheduled for February 2005.

The basis for Mexico's and Canada's ultimate decision to hold the workshop was a jointly held perception that the key (in part) to effecting tangible progress in the forthcoming Regime negotiations lay in: further elaborating the "problematic" of the International Regime; enhancing understanding of the current state of ABS policy-making at the domestic, regional and multilateral levels; and, identifying and critically examining both conventional and new "solutions" to the problems at hand. It was agreed that the Workshop would steer clear of explicit recommendations and that the co-hosts would make every effort to encourage open, frank, and unattributed debate in a neutral, thoughtful setting.

A compelling contextual factor was Canada and Mexico's common desire to quickly and constructively act upon Decision VII/19 of the COP, calling upon Parties, Governments, organizations, indigenous and local communities and all relevant stakeholders to provide information and views on a range of ABS-related matters.

The Workshop was not intended to be a negotiating forum and participants were invited in personal capacities as recognized experts. This was well understood by all participants throughout the Workshop in Cuernavaca - a credit to their professionalism and aided by the venue chosen to host the meeting.

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[1] The following reflections are solely those of the co-authors and not of their respective agencies or governments.

The Meeting

The Canada-Mexico Workshop was organized to consider both "big picture" issues, as well as the more specific issues that an International ABS Regime would touch upon.

During the first day of the Workshop, panelists and participants reflected widely on the state of national ABS policy implementation around the globe (including the challenges of monitoring and enforcing access regulations and better understanding biopiracy/misappropriation), as well as the vision and nature of an International ABS Regime (i.e., goals, challenges, gaps and the role of the CBD and other bodies).

The second day of the Workshop witnessed an extended and dynamic discussion on a host of intellectual property rights issues related to genetic resources and traditional knowledge.

The third and final day of the Workshop included invigorated discussions on mechanisms for monitoring and/or verification (including certificates of legal provenance/source/origin), and finally on ways and mechanisms to ensure benefit-sharing.

Reflections

In our experience, the level of discourse maintained throughout three days of extensive sessions was remarkably high. To be sure, participants had the distinct advantage that they were neither advocating particular positions nor negotiating the International Regime. Equally, however, the substantive reach of the experts and the very positive tenor of discussions may also be attributed to the widely-held sentiment that deliberations in Cuernavaca had the potential to make a long-lasting contribution to global ABS policy-making and the negotiation of an International ABS Regime.

It was clear from the outset that the Workshop's agenda was extremely broad and, potentially, overly ambitious. On the other hand, it was our view that the Workshop should not limit the subjects for discussion or debate. Experts were "priming the pump", either initiating or advancing discussions but not concluding them.

We strongly recommend all to read the attached record of discussions and the many presentations and discussants papers prepared especially for them.

On the basis of the attached documents, we turn attention briefly to a number of areas requiring further analysis and reflection by experts and others. We note, however, that the following is by no means a comprehensive or prioritized list.

The issue of the *objectives* of an International Regime was touched on time and again over the course of the Workshop. The objectives of the Bonn Guidelines and the CBD itself were mentioned in this context. Views, however, are surprisingly diverse on this question and, indeed, the International Regime may prove in the end to be truly multidimensional in both objectives and scope. While negotiators will necessarily focus on this critically important issue in formal talks, there is merit in considering the objectives (and perhaps principles) of the International Regime outside the negotiations proper.

Linked to the question of objectives is the challenge of *designing and constructing* the International Regime. It is true, again, that negotiators will need to determine the ABS Regime's ultimate structure. These final determinations are clearly some way off and so the time is ripe to gather policy and legal experts as well as stakeholders together, and consider the complexities of design and the plethora of possible approaches and instruments. The interrelationships among existing relevant instruments and initiatives will be particularly challenging in the design of the International Regime

and, indeed, warrant further study and discussion. National experiences and sub-national ABS policy experiences are also important footings for building an international framework.
There is a growing interest among many experts in further refining models for a system of *Certificates of Origin / Legal Provenance*. Further elaboration of such models and greater expert debate on the potential advantages and limitations is clearly desirable. It would be an obvious and important subject for any future experts' workshop.

An ample number of other issues require further consideration. Included, for example, would be *administrative measures, derivatives, voluntary user measures, capacity-building, disclosure of origin and the intersection between International Regime and national/sub-national ABS policies*. All are substantive issues in their own right and negotiators, in our opinion, would be greatly aided by further research, analysis and debate on these subjects.

The *interests, rights and participation of indigenous and local communities* are clearly important subjects. Workshop experts acknowledged that the involvement of indigenous peoples themselves in discussions of genetic resources and associated traditional knowledge should be a prerequisite. Among the suggestions for a path forward in this regard included the idea of holding a separate workshop on indigenous issues as a way of advancing understanding, building capacities and improving participation of indigenous and local communities (as called for in COP7 decisions).

Follow-up

The attached Workshop record, panelist presentations and discussant papers will be transmitted to the CBD Secretariat for dissemination as an information document in advance of the third meeting of the Open-ended Ad Hoc Working Group on ABS. It is our plan to sponsor a "side event" at this meeting to review the Workshop results.

It is our sincere hope and expectation that others will pick up where the Canada-Mexico Workshop left off. As the Cuernavaca meeting demonstrated, the post-COP7 intersessional period affords an excellent, perhaps unique, opportunity to fill in research gaps and advance our understanding of existing problems and the range of possible solutions. Such meetings encourage inter-regional co-operation, bring together a diverse range of experts from many fields and sectors (who otherwise might never meet) and provide an open, informal forum in which to consider highly complex and technical issues. On the basis of the Cuernavaca meeting, we recommend our experience to others.

Acknowledgements

The Co-Chairs wish, first, to thank the Workshop participants - many of whom travelled long distances and all of whom devoted significant time and intellectual energy in preparing and discussing a broad range of very complex issues. Both individually and collectively, these experts have made substantive and long-lasting contributions to international ABS policy- making. We are most grateful to their participation and subsequent agreement to publication of their panel and discussion papers.

To our co-sponsor, the Government of Switzerland, we extend special thanks for the crucial funding it so generously provided. We offer a personal note of gratitude to Francois Pythoud of the Swiss Agency for the Environment, Forests and Landscapes (SAEFL) for his substantive contributions to the Workshop.

We must also acknowledge the pivotal funding and support for the Workshop and follow-up activities provided by the Canadian International Development Agency, Foreign Affairs Canada (FAC), the Instituto Nacional de Ecologia (INE), the International Development Research Centre (IDRC), and the Secretaria de Medio Ambiente y Recursos Naturales (SEMARNAT).

We would like to thank Mariana Bellot and Martha Rosas of the National Commission for the Use and Knowledge of Biodiversity (CONABIO) in Mexico, and Sophie Bernier of Environment Canada, without whom the meeting could not have taken place.

A heartfelt thanks to our facilitator Tom Hammond and rapporteurs John Mundy, Sophie Bernier, Mariana Becerra Pérez and Gmelina Ramirez Ramírez – all of whom worked ceaselessly through the days and tirelessly late into the nights.

Finally, we wish to acknowledge the instrumental role played by Jock Langford of the Biodiversity Convention Office of Environment Canada and José Carlos Fernández Ugalde of the National Institute of Ecology (INE) in Mexico. The Cuernavaca meeting was in large part their conception and the Workshop's many successes are in large measure theirs. The meeting stands as a credit to the limitless intellectual capacities and the strong personal commitment these two individuals bring in their quest to advance ABS policy.

Sincerely,

Timothy J. Hodges
Environment Canada

Jorge Soberón Mainero
CONABIO

2. Generating new Ideas and Thinking: Record of Discussions

Generating New Thinking and Ideas: Record of Discussion

Opening Remarks

The two co-chairs, Jorge Soberón Mainero of Mexico and Timothy J. Hodges of Canada, welcomed participants to the Workshop and thanked the organizers and sponsors of the meeting, which included the governments of Canada and Mexico and their agencies, and the governments of Switzerland. They hoped for a wide-ranging and vigorous discussion which would identify areas of agreement and also of disagreement on issues related to access and benefit-sharing (ABS). The intention of the organizers was to prepare a report on the meeting, which would be transmitted to the Secretariat of Convention on Biodiversity (CBD) as a contribution to further work and negotiations on an International ABS Regime.

Substantive Discussion

I. Identification of Outstanding ABS Issues

Level of National Implementation

Speaker: Valérie Normand
Paper: National Implementation

Speaker: Santiago Carrizosa
Paper: Developing and Implementation ABS Regulation in the Pacific Rim Region: Issues and Challenges

The two papers provided information about the level of activity, both globally and specifically within Pacific Rim countries, on developing national ABS policies and regulations. While action is underway in many countries, relatively few have completed the development of a policy framework and/or legislation. Issues for consideration in the paper included: How broad should the scope of legislation be? How should ownership of *ex situ* collections be defined? How could prior informed consent procedures be improved? Also considered was the need for effective monitoring systems and conflicting views on patenting of life forms. It was noted that initial approaches to ABS legislation tended to follow a top-down approach rather than a more community-level approach.

Main issues and concerns

- Progress in the implementation of the CBD at national level is difficult to assess since it involves many laws and regulations not necessarily related directly to the CBD
- There may be too strong a bias towards CBD-related concepts

The subsequent discussion focused on two main issues. First of all it was noted that too strong a bias towards CBD-related information ran the risk of missing a great deal of information and experience on ABS which was either not directly related to the CBD or which originated prior to active work on ABS in the Convention being undertaken. It was noted for instance that most countries had access laws, but that these were formulated in a multiplicity of regulations and permits (e.g. research permits, collecting statements, export permits, etc.) rather than as a framework law on ABS alone. This information is still valid and relevant to work done on an International Regime and ways should be found to collect it. It was also noted that while there was a multiplicity of laws and regulations governing access, there was much less governing benefits.

The second main point also picked up on the theme of too much bias towards CBD-related concepts, arguing that it should not be assumed that an International Regime on ABS under the CBD is the best way forward. There were concerns for improving equity, redistributing wealth more widely, and protecting spiritual and cultural values associated with genetic resources.

National Access Laws (Challenges): Continuing Monitoring and Enforcement Issues

Speaker: Paz Benavidez
Paper: The Challenges in the Implementation of the Philippine ABS Regulation: Monitoring and Enforcement of Bioprospecting Activities in the Philippines

This paper describes the experience with Executive Order 247 and the current efforts to revise the approach through developing guidelines under the Wildlife Resources Conservation and Protection Act. There are many challenges, not least being the development of an effective monitoring and enforcement system which implies finding ways of enforcing agreements outside the Philippines, including coverage of transfers to third parties.

Speaker: Geoff Burton
Paper: National Access Laws: Challenges, Benefit-sharing, Monitoring and Enforcement

The paper outlined that Australia's approach to introducing national access laws within it's federal structure of government, encapsulated in an intergovernmental agreement entitled *the Nationally Consistent Approach for Access to and Utilization of Australia's Native Genetic and Biochemical Resources Act*. The Australian experience was informed by several observations including: the sensitivity of biological research to barriers; the serendipitous nature of research outcomes which argues for encouraging high volumes of research; the need to take the undervalued genetic resources in the global commons into account; and, the danger that policy responses lag substantially behind scientific progress.

Speaker: Robert Lettington
Paper: Briefing Note: National Access Laws (Challenges)

In the Kenyan experience there was a great need for more clarity on the objectives of ABS policies, identification of a national authority, the definitions of key terms including 'genetic resources' and a recognition that different sectors require different approaches (e.g., more control might be needed over endemic species compared to non-endemic species).

Main issues and concerns

- There seems to exist considerable overlap across different international organizations regarding ABS policy-making, which generates uncertainty for industry

- Different forums and international agreements have a constructive role to play for the development of an IR on ABS
- Competing legal jurisdictions as a basis for contractual arrangements between provider and user countries may cause barriers to both parties
- Efforts to promote bio-prospecting activities to develop and extend knowledge of a country's genetic resources, and efforts to develop a policy framework to govern ABS, are not mutually exclusive
- Building up local capacities and abilities should form a main part of benefit-sharing agreements, rather than simply focusing on royalty benefits which are long-term and uncertain

In the subsequent discussion, some of the concerns expressed by industry, such as the negative impacts of uncertainty, the lack of transparency and long time delays were underlined. This may have contributed to the pharmaceutical industry increasing its emphasis on combinatory chemistry. Uncertainty was aggravated by that fact that there are too many different international organizations making policy in the ABS field. On this last point, there was also recognition that different forums and international agreements had relevance to various aspects of a potential International Regime on ABS and that they had a constructive role to play.

The issue of competing legal jurisdictions was also raised and it was recognized that key developed country legal jurisdictions were likely to be the basis for contractual arrangements on ABS. This would imply that parties to a contract would be dealing with two different legal systems. While this might be inevitable, it raised the issue of access by source countries to legal jurisdictions and, in particular, what barriers developing countries faced. For instance, how would developed country jurisdictions recognize the national laws of provider countries including their customary law practices?

Another issue raised was the sequence of effort. Should the focus be on promoting bio-prospecting activities to develop and extend knowledge of a country's genetic resource base or should effort go into developing a policy framework to govern ABS? It was suggested that these efforts were not mutually exclusive and that one of the goals of a policy framework would be to encourage the development of this type of knowledge.

Finally there was a discussion about the nature and timing of benefits. Some thought that royalty benefits were potentially illusory as well as being very long term. Disputes over the rate of royalty to be charged depended upon a clear answer to the question concerning the base for it to be calculated upon. Benefits that focused upon building up local capacities and abilities were potentially easier and faster to obtain.

Access to Genetic Resources and Intellectual Property Rights: What is Biopiracy?

Speaker: Graham Dutfield
Paper: What is Biopiracy?

The paper provides the context for a discussion on 'biopiracy'. There is a perception amongst developing countries and NGOs that the patent system enables corporations to misappropriate genetic resources and associated traditional knowledge or at least to unfairly 'free-ride' on them.

The paper seeks to shed some light on the meaning of the term "Biopiracy" and to consider what should be done about it, bearing in mind that an agreement on what is and isn't biopiracy —and how much of it there actually is— is still lacking. While there may be valid reasons for the 'strategic vagueness' of the concept, it is a problem for those working upon legal solutions. Views vary considerably on what the term means and the challenge is to find an effective middle ground.

Main Issues and Concerns

- There is no agreed concept of "biopiracy", It could be defined and standardized under the IR and/or allow countries to define it at the national level
- A biopiracy framework could address three levels: violation of prior informed consent procedures, violations based on mutual agreements, and third party issues
- "Biopiracy" may be defined as the illegal appropriation of values, when illegal access to biological resources is obtained, etc.
- The IR should aim for fairness and equity, as the perception of biopiracy is partially driven by experience rooted in exploitative colonial arrangements
- The concept of 'strategic vagueness' may be useful since it is important for countries to define what is legal and illegal according to their own circumstances and then find effective ways of enforcing it

In the subsequent discussion, it was recognized that there is no agreed definition of biopiracy and that each country would define it according to its own perspective. The key issue was if the international community was going to do something about it. How does the international community take action while acknowledging that some countries have very tough standards and others are more liberal? Should this be undertaken under the CBD or outside of it?

Biopiracy could be defined as when illegal access to biological resources is obtained. It would also be important to differentiate between organized illegal activities and opportunistic illegal activities. A biopiracy framework could address three levels: violation of prior informed consent procedures, violations based on mutual agreements, and third party issues.

When we consider biopiracy we should ask what has been taken. It is not DNA because this moves about freely, nor is it the knowledge of genetic resources. It is the value that lies in traditional knowledge and genetic resources. Biopiracy could be defined as the unauthorized appropriation of values.

The definition of biopiracy is very important. Should the proposed International Regime address it or leave it to national legislation? It was recognized that there were too many polemics on biopiracy and that the paper very usefully deconstructed the concept.

It was suggested that we needed to define the objective of an International Regime and be clear about what we are trying to achieve. Aiming for fairness and equity is very important. The key challenge was to define those principles.

It was noted that biopiracy is not a new phenomenon. What has changed is the perception of biopiracy, which is driven partially by experience rooted in exploitative colonial arrangements. A question was raised on whether contravening ABS laws necessarily implied biopiracy. More generally, when there is illegal behaviour, is it biopiracy? Answers could lie in copyright law.

Finally, it was suggested that the concept of 'strategic vagueness' was a useful one. Reaching an internationally agreed definition was an academic problem. What was important was for countries to define what was legal and illegal according to their own circumstances and then find effective ways of enforcing it.

II. Vision and Nature of an International Regime: Goals, Challenges, Gaps and Role of CBD and Other Bodies

Vision and Nature of an International Regime

Speaker: François Pythoud
Paper: Vision and Nature of an International Regime on ABS

The paper focuses on the main questions that should be addressed when developing an International Regime on ABS. It refers to CBD Decision VII/19, which identified 21 elements for inclusion in the International Regime under the terms of reference. The paper groups them into 6 categories, which provides a framework of the main elements of the International Regime, whose scope would cover both genetic resources and traditional knowledge. It also raises the important question of whether the International Regime should be integrated with other pertinent legally-binding and voluntary instruments, or be independent.

Speaker: Tomme Young
Paper: The International Regime from an Implementation Perspective: What Legislation can... (and cannot do) and How this Affects the Vision and Nature of the Regime.

The paper focuses on two basic questions: what is possible from a legal perspective and what is needed to enable "the possible". An important goal in the negotiations of an International Regime should be the development of a roadmap for the solution of legal impediments that currently inhibit implementation. At a minimum this should address the needs of functional ABS law and utilization of the tools of commercial and market-based (contractual) frameworks. The paper notes that while the ABS framework of issues is closely linked to biosafety/GMO frameworks, national and international legislation on these two issues is almost completely separated. Re-linking them might create real commercial incentives for both.

Speaker: Joshua Rosenthal
Paper: Power Point Presentation

The presentation provided information on the approval of new drugs in the United States during the period 1981–2002. Only 6% of all new FDA approved chemicals are derived directly from natural products, while 49% have some relation to natural derivatives. The absolute number of new drugs approved is relatively low and the data shows that the rate of approvals is dropping. From the high point in 1987 (70 new drugs), only 27 new drugs were approved by the FDA in 2002. Information was also provided on the ICBG-NIH project. Despite 10 years of work, some US$30 million of funding, the work of many partners and the review of 500 compounds, no new drugs have been created. This demonstrates that potential pharmaceutical benefits from natural products are not as great as sometimes envisaged and related potential royalty flows could be disappointing. The ICBG experience also demonstrates the substantial impact of transaction costs. Finally an International Regime should balance property interests with the need to enhance information flows and increase their public availability.

Speaker: Stephen Smith
Paper: The International Regime as it Applies to Plant Genetic Resources for Food and Agriculture

The paper discusses ABS from the perspective of plant genetic resources for food and agriculture (PGRFA), including the features and limitations imposed by history, biology and laws. It relates to the special needs of this sector to an International Regime on ABS and stresses that continued access to PGRFA is critical to human health, economic sustainability and the environment. An International Regime should promote more effective access to and use of PGRFA. The FAO's

International Treaty and the CBD provide complementary paths forward. The needs of both providers and users of genetic resources must be met in order to ensure that the continuum linking farmers to consumers is maintained. An International Regime with legal certitude will remain non-functional unless additional resources are applied to identify potentially useful exotic germplasm.

Speaker: Peter Einarsson
Paper: Oral presentation

The presentation focused on the situation and rights of people who are directly dependant upon biodiversity for their livelihood (approximately 1/3 of the human population, including Indigenous people and farmers). The International Regime must address the fear in these communities that access will be provided widely but the benefits shared only between governments and users. In this regard, the Johannesburg Declaration, which focused on benefit-sharing, and both Article 15 and Article 1 of the CBD, are all relevant. There was a danger that the work being done on an International Regime will focus too narrowly on commercialization. Achieving fair and equitable treatment was a very difficult challenge when the different parties come from such different power positions. The inequality of actors should be recognized and addressed. A relatively narrow focus on disclosure of origin, without effective prior informed consent and monitoring, might serve only to legitimize inequitable exchanges of genetic resources.

Speaker: Robert Lettington
Paper: Vision and Nature of an International Regime: Minimum Requirements and Options from a Practical Developing Country Perspective

The paper addresses the core objectives of an International Regime. Too much complexity should be avoided. User country measures and the related questions of enforcement and compliance are the central issues to be addressed by an International Regime. The paper discusses monitoring mechanisms, minimum standards and the need for categorization of the various uses of genetic resources. It also addresses the supporting components of an International Regime including information clearing, monitoring and capacity building. The main challenges to developing an International Regime are overcoming polarized views of various actors and improving national capacities. Greater attention to capacity-building, combined with effective user measures, will allow developing countries to comfortably engage in collaborations with developed country actors.

Main issues and concerns

- Overemphasis on the pharmaceutical model of access to genetic resources in the international debate
- Area of botanicals as one of market growth was highlighted
- We have a problem of a non-enforceable rather than a non legally-binding agreement, since the CBD is legally-binding
- Need for a clear distinction between the treatment of GR and TK in the IR
- Lack of capacity, political will and conceptual clarity has impeded progress in ABS, but the IR offers a renewed political momentum
- Two general approaches to delimitate an effective IR: a *holistic* approach with a wide range of objectives and coverage of all stakeholders or a *staged* approach, which addressed specific issues
- The *holistic* approach based on a philosophical discussion focusing on the core objectives of the CBD may be an essential precondition to developing an effective IR, while the *staged* approach was suggested as being more practical

- Need to resolve whether the core objectives of the CBD focus on maximizing commercial benefits or on conservation and sustainability
- "Strategic incoherence" may have a positive impact on ABS, public interest and public gain because it leaves parties with the flexibility to implement ABS measures that meets national and local needs
- The objectives of harmonization and minimum standards are contentiously feasible in the short term due to the fast pace in which scientific developments are taking place
- If considered an essential element of an IR there is the need to define what are the certificates of origin, to have the ability to model them, and to determine what potential costs and benefits they would provide
- An IR should provide developing countries with access to knowledge, which would enable them to add value to their own resources, and which would ensure compliance by user countries to active ABS legislation

In the initial discussion, which took place after the first three presentations, there was debate about whether we are focussing too much on pharmaceuticals. Many participants discussed the importance of botanicals. Questions raised regarding botanicals included whether the interest was in their genetic resources, or was it more strongly related to the need to purify botanical compounds? The market for botanicals has grown in the past couple of years, but few arrangements are treated as CBD-ABS contracts since they tend to be treated as commodity transactions.

A discussion about the danger of confusing the concept of a legally binding agreement with an enforceable agreement followed. The two concepts were not equivalent. There is also the potential for mixing binding and non-binding elements together in a possible International Regime.

It was noted that this Workshop was more focused on genetic resources than on traditional knowledge. We were reminded of recent negotiating history on traditional knowledge, particularly as it applied to the negotiation of CBD COP Decision VII/19. Until corrected by negotiators at COP VII, this decision in draft form had treated traditional knowledge incorrectly as something being under the jurisdiction of States. Traditional knowledge is under the exclusive jurisdiction of Indigenous peoples. There must be a clear distinction between the treatment of genetic resources and traditional knowledge in an International Regime. It was also noted how intimate was the interplay between traditional knowledge and the identification and use of genetic resources. From the perspective of traditional elders, there is no clear distinction between a resource and the knowledge associated with the resource.

There was also a discussion about basic approaches to an International Regime. What is the basic objective? Will it be made up of hard law and soft law? Should the regime draw in other institutions by reference or attempt to give them direction? How will the International Regime relate to the objectives of the Johannesburg Declaration? Should it be negotiated in one comprehensive and complete form or should the negotiations and implementation be staged or progressive?

Finally, participants discussed the importance of political will. Data on progress towards creating ABS policies at the national level might suggest that there is insufficient political will. Others thought that there was significant political momentum behind ABS but that a lack of capacity at the national level and a lack of clarity in the concepts impeded progress. There was potential for the negotiation of an International Regime on ABS to act as an enabler at the national level.

The second part of the discussion focused upon trying to delineate the different elements of an effective International Regime, based on simple and clear goals. There were two general approaches: a *holistic* approach with a wide range of objectives and coverage of all stakeholders or a *staged* approach, which addresses specific issues.

Many thought that the second option was more practical, although others thought that a philosophical discussion focusing on the core objectives of the CBD (Article 1) was an essential precondition to developing an effective International Regime. While there was a presumption that the CBD should maximize commercial benefits, the CBD's core objectives focus on conservation and sustainability. This tension needs to be resolved.

Further discussion noted that tension between objectives as they relate to ABS, public interest and public gain, was not necessarily an impediment. It meant that a balance between different objectives needed to be defined. "Strategic incoherence" could be a positive thing because it left parties the flexibility to implement ABS measures which met national and local needs.
A general political declaration was suggested to the effect that no profits should be derived from illegal activities. It could be left to individual governments to work out how to implement this, according to their own circumstances.

There was also discussion about harmonization and minimum standards. There was disagreement about whether these objectives were feasible in the short term because of the accelerating pace with which scientific developments are taking place.

There were different opinions about the concept of certificates of origin. Some thought that they would be an essential element of an International Regime. Others thought that the concept of certificates had not yet been properly developed. Before negotiating on certificates we had to know what they were, have the ability to model them and determine what potential costs and benefits they would provide.

An International Regime should provide developing countries with access to knowledge, thereby enabling them to add value to their own resources. It should also ensure compliance by user countries to ABS legislation put in place in provider countries. This could be formulated as substantive compliance with national laws through transparent conduct.

III. Specific Issues for Consideration in the Elaboration of the IR Interface with Existing IP System and Limits and Opportunities for Existing IP Rights

Speaker: Martin Girsberger
Paper: Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications.

This paper analyses several issues connected to, and contains proposals for a way forward with regard to, the declaration of the source of genetic resources and traditional knowledge in patent applications. The issues considered include: what terminology should be used to cover genetic resources and traditional knowledge; how should the concept of "source" be defined; what should trigger a disclosure requirement; what is the legal basis of the disclosure requirement; should voluntary or mandatory disclosure be required at the national level; and what sanctions could be considered for failure to disclose or wrongful disclosure. The paper draws a number of conclusions based on the recent Swiss proposal submitted to the WIPO working group on Reform of the PCT.

Speaker: Kim Connolly-Stone
Paper: The Interface with Existing Intellectual Property Systems: Limits and Opportunities for Existing Intellectual Property Rights

The paper considers relevant aspects of the CBD and the WTO on Trade Related Aspects of Intellectual Property Rights (TRIPS), with a view to determining what flexibility exists under TRIPS to take national measures in support of ABS objectives, including prior informed consent (PIC), mutually agreed terms and benefit-sharing. Particular attention is given to the various proposals in favour of disclosure of origin or source of genetic resources and associated traditional knowledge, and evidence of PIC or benefit-sharing, in applications for patents and plant variety rights (PVRs).

It concludes that the IP system can support ABS through disclosure, in addition to ABS systems of disclosure and other areas of law. Parties should take advantage of the flexibility available under TRIPS to provide policy space to implement ABS policies. The IP system could also require mandatory disclosure of the source of genetic resources and associated traditional knowledge in applications for patents and PVRs and collect information about whether PIC and benefit-sharing has occurred, but this should not become a substantive requirement for patentability. If disclosure of PIC and benefit-sharing is required, however, an amendment to TRIPS would be needed. Some difficult areas to address included: defining the trigger for disclosure, prescribing suitable documentation, minimizing compliance costs, achieving progress in TRIPS Council and combating the effect of free trade agreements which required parties to opt out of TRIPS flexibility provisions.

Speaker: William Kingston
Paper: Four Reforms for Wider Benefit-Sharing

The paper focuses on advocating reforms of intellectual property rights to contribute to the protection of genetic resources and traditional knowledge as well as to benefit-sharing. The present system of intellectual property rights is effectively a unitary system based on the United States approach, more diversity is needed. The present system has developed in ways which reinforce the market powers of capability and persuasion which advanced-country firms possess in strength. Other countries need intellectual property rights which compensate for their weakness in these types of market power. The four reforms are: returning to states the power to limit the absolute monopoly which trade marks deliver, direct protection of innovation, compulsory arbitration of disputes, and introducing a financial dimension into the measurement of all grants of intellectual property rights.

Speaker: Ruth Okediji
Paper: Access and Benefit-sharing and the Interface with Existing IP Systems: Limits and Opportunities

The paper comments on a number of issues where the interface between intellectual property rights and ABS offer possibilities for developing the framework of an International Regime on ABS. Concerns about the incompatibility of intellectual property and traditional knowledge that revolve around the concept of value should be reconsidered in the light of the protection of non-economic values already existing within the intellectual property system. There is also considerable overlap between copyright, patents and trademarks or trade secrets. A single product could have many overlapping rights. Traditional knowledge could benefit immensely from this. The possibility of patenting some forms of traditional knowledge may compel a legal framework that can straddle both a *sui generis* system of protection at the national level and the international intellectual property system.

Furthermore, the possibility of an International Regime outside the intellectual property system raises the question of appropriate legal baselines. One baseline is a property rule regime, which has been the dominant choice for international intellectual property treaties. A second baseline is a liability rule regime which allows use to occur through implicit license with the appropriate compensation being determined subsequently. Features of both regimes could coexist in the same system. While most existing proposals for a *sui generis* ABS International Regime are based upon the property rule, the possibility of a liability regime could be a serious alternative, particularly for traditional knowledge. It would also address the problem of high transaction costs. Finally the paper notes that the availability of alternative legal sources for intellectual property rights creates an "opt-in" system where creators essentially choose the type of protection model suitable for their interests.

Main issues and concerns

- Disclosure of origin alone does not create a compensatory right within or outside IR, further measures should be taken
- Focus should be on contractual arrangements that guarantee benefit-sharing at earlier stages, rather than benefits such as royalties over the long term
- Voluntary disclosure in ABS would not need a TRIPS amendment, however mandatory disclosure could be needed
- Countries requiring disclosure in their national legislations would help move the debate forward
- A certificate of origin as proof of PIC would reduce administrative burden of IP offices
- Disclosure requirements could provide incentives for provider countries to facilitate access
- Trademarks could be a useful instrument to provide protection to TK
- There is a danger of putting unnecessary constraints on achieving CBD objectives if IR was contained in a IP/TRIPS dilemma
- Too much emphasis on disclosure could give providers a false sense of security
- The relationship between disclosure and benfit-sharing should be closely looked at
- There could be a need for harmonization on triggers for disclosure
- A transparent, easily enforceable system, which provided certainty to users, could be an incentive for industry to comply with an IR
- There are two approaches for disclosure: an administrative measure or as a substantive condition for patentability

During the first part of the discussion, which took place after the first two presentations, it was pointed out that disclosure alone does not create a compensatory right. The Yellowstone Park experience was relevant as the Park did not have a compensatory interest despite disclosure. In addition, it was asserted that disclosure should apply within and without the patent system if it captures different forms of innovation. Norway is also considering the addition, to its national legislation, of a requirement of proof that benefit-sharing was achieved.

It was noted that the pharmaceutical industry supported disclosure, although it should be kept in mind that because of long lead times, most potential benefits would have already come and gone by the time a product was approved for market. There should be a focus on contractual arrangements which provide for benefit-sharing at earlier stages.

Finally the concept of "essentiality" was raised. In those cases where an innovation might be based on many different compounds, only one of which was deemed essential, it was confirmed that the Swiss approach could encompass disclosure of the essential element only.

There was also a recognition that TRIPS amendments would be difficult and time consuming to obtain. There was debate about whether purely voluntary disclosure of ABS related information required a TRIPS amendment and the conclusion was that it did not. However, some thought that a voluntary system would not have much effect and that mandatory disclosure was needed which would in turn require a TRIPS amendment. On the other hand if a few important user countries required disclosure this would be influential.

It was proposed that a certificate of origin could be designed as proof that PIC had been obtained. This might reduce the administrative burden on patent offices. In addition, one way to encourage continued flexibility in the IP system was to include the need for flexibility in an ABS International Regime. This might help address the problem of TRIPS flexibility provisions being dropped in FTAs. It was also noted that disclosure requirements would act as incentives for provider countries to better grant access to genetic resources to user countries.

In the final discussion it was suggested that an additional reform could be to use aid funds in cases where intellectual property rights might be bought out to further a development goal. It was suggested, however, that this might just encourage further challenges by intellectual property holders.

It was noted that trademarks were useful instruments that could be used to provide protection —particularly for traditional knowledge— and that American indigenous groups were using them. However, there was less applicability to genetic resources because products so derived were not typically marketed according to their source.

There was finally discussion about the danger of an ABS International Regime being contained within an IP/TRIPS paradigm that might impose unnecessary constraints on achieving CDB/ABS objectives. It was noted that the existing intellectual property system was not fostering innovation but rather protecting investment. There was another view that criticism of TRIPS and the current intellectual property system ran the risk of "throwing the baby out with the bath water". While there is a need for a better balance between public and private interests, criticism of trademarks undervalued the benefits of the attention to quality standards, which a trademark implied.

Participants also debated about the intellectual property system and the role it could/should play in an ABS regime. Some thought that the intellectual property system was very elastic and could perform different roles depending upon national objectives. Others thought that trying to find a sufficient level of flexibility within TRIPS for ABS needs should not box in the International Regime. It should be possible to develop the International Regime for its own specific goals. For instance, benefit-sharing and the protection of traditional knowledge should not expire with the end of a patent term.

There was concern that too much emphasis on disclosure through the patent system would give providers a false sense of security. A patent in itself did not imply benefits. For instance, a patented drug was worthless unless approved by the drug authorities. Patents do not cover many forms of innovation. Innovation can rely for instance upon trade secrets for protection, which can last indefinitely.

There were some doubts about the true value of the disclosure of origin. Without knowing its true value, it will be hard to calibrate the negotiating price to pay for it. There was also concern about mandatory disclosure requiring a TRIPS amendment, which most thought would be very difficult to obtain.

It was noted that there is a need for harmonization on triggers for disclosure. The fears of plant breeders were also raised because their products originate from hundreds of different sources, which would be very difficult to identify and properly disclose.

It was suggested that a music industry model might be compatible with a liability regime whereby users of genetic resources and traditional knowledge paid a fee to a collection agency in the same way that radio stations paid for music.

It was thought that the key to benefit-sharing was a system of incentives for users of genetic material and traditional knowledge. There was the example of the Orphan Drug Act in the United States, which broke existing intellectual property laws by allowing the National Health Office to ensure, for a defined period, that no licenses be granted to competitors of anyone that had developed eligible drugs meeting the national need to combat obscure illnesses. The results were good.

There was discussion about the incentives needed for industry to comply with an International Regime. It was noted that compliance measures had to be balanced with incentives. It was noted that developing a transparent, easily enforceable system, which provided certainty to users, would be enough incentive for industry. Referring to the example of plant variety protection systems, it was noted that the intellectual property system alone could not deliver enough incentives to promote wide-ranging research. This had to be delivered by the public sector. Consequently when commercialization occurs, benefits should be invested back into research. It was suggested that the International Regime had to have a balance between incentives (the carrot) and the intellectual property system (the stick). There were two ways of using the patent system for disclosure. There was pure disclosure at the administrative level only and disclosure, which became a substantive requirement for patent. The second approach could put unrealistic burdens upon patent authorities.

Limits to Rights over Genetic Resources: the Issues of Derivatives. Defining the Line between Tangible and Intangible Property Rights

Speaker: Fernando Casas
Paper: Genetic Resources Property Rights. The Derivatives Issue. Tangible and Intangible Property Rights

The paper examines the potential ABS International Regime, benefit-sharing, property rights on genetic resources and their derivatives, in light of the Andean experience. The concept of derivatives is defined as well as the size of the market opportunity. The main actors include: the Nation State, business, Indigenous peoples and the scientific community. Particular issues addressed include: the limits to rights, the role of the State, genetic resources and derivatives, provider rights, user rights, non-material or intangible property and traditional knowledge.

Main issues and concerns

- Genetic resources are not only genes but a wider range of material such as molecules and enzymes
- Defining the term "derivatives" has proven to be very complex. Concept could be recaptured under a different term
- As live forms are increasingly becoming private property, the issue of derivatives should be addressed within the IR

In the subsequent discussion, it was recognized by many that this was a very complex issue and one that could not be avoided in the elaboration of an International Regime. It was underlined that genetic resources are not just about genes. They include a much wider range of material (molecules, enzymes, etc), which are the basis of derivative products with a very large market value. Derivatives are also strongly connected to traditional knowledge.

It was noted that defining the term "derivatives" was very difficult. There was a continuum starting with original material, progeny, unmodified derivatives (ie, genes) and modifications. The US NIH attempted 10 years ago to define how far along this continuum providers could claim control before ownership be transferred to the user. Other speakers also recognized the difficulty of finding a clear dividing line.

It was noted that in the academic world there was a great deal of exchange and modification of genetic material and that it would be extremely difficult to develop an administrative structure that captured and reported upon this scientific activity. It was noted that derivatives was not a definitional problem but a political and conceptual problem.

It was unlikely that the international community could reach an agreement on its meaning. Neither the CBD nor the FAO International Treaty was able to do it, despite much effort. We have an expanding world of private rights, which are rolling back the public domain. The issue for the International Regime revolves around whether it should encourage this development, brake it or attempt to reverse it. It was suggested that we should concentrate on conceptually mapping the concept and then find a different word to cover it.

A participant warned that derivatives should not include coverage of research tools in areas of biotechnology because this would have a huge chilling effect on research. Another participant noted that we are living in a transitional society where life forms are becoming private property. Asymmetry between countries is growing. Addressing derivatives in an International Regime is essential.

New Forms of *Sui Generis* Protection Relevant for the International Regime (Genetic Resources and/or Traditional Knowledge)

Speaker: Graham Dutfield
Paper: New Forms of Sui Generis Protection

The paper focuses upon a *sui generis* system of protection applicable to traditional knowledge. It stresses that such a system must respect the holistic and collective nature of traditional knowledge. It can only be developed with the close collaboration of traditional knowledge holders and their communities. It suggests that a CBD-related system should probably limit its scope to coverage of traditional knowledge associated with biological resources or with the environment more generally. Such limited scope would make consensus easier to achieve but can also be dangerous. On the one hand, a harmonized system cannot easily accommodate diversity, which might render the system useless. On the other hand, a system tailored to a few ethnic groups might alienate other Indigenous peoples. The paper provides a check list of key points for negotiating and policy making in this area.

Speaker: Jock Langford
Paper: Sui Generis Protection of Genetic Resources and Associated Traditional Knowledge

This paper considers the issue of *sui generis* protection of genetic resources and associated traditional knowledge from three perspectives:

(1) *sui generis* protection of genetic resources under national access and benefit-sharing law, (2) *sui generis* intellectual property protection of genetic resources and traditional knowledge, and (3) *sui generis* protection of genetic resources and traditional knowledge outside the scope of intellectual property rights. With the first perspective, there seems to be development of two systems, one focused upon creating national level *sui generis* property rights based upon the principles of prior informed consent (PIC) and mutually agreed terms (MAT) and a second regime based on Indigenous and local community PIC for accessing traditional knowledge and associated genetic resources. Regarding the second perspective (2), the paper identifies areas of intellectual property law that are more readily adaptable to protecting genetic resources. These could include application of the IP concepts of: appellations of origin, data protection for confidential business information which could be applied to traditional knowledge and possibly some forms of taxonomic data, and certification systems including the possibility of a CBD certification mark. Regarding the third

perspective (3), Article 8(j) of the CBD affords an opportunity to develop *sui generis* systems of protection recognized under national law that resemble the customary laws and traditional protocols of Indigenous communities.

Main issues and concerns

- An IPR system could be used as a complement tool for protecting TK, but other mechanisms should be in place
- TK is strongly connected to the land rights of Indigenous peoples and TK protection should embrace both
- Participation of Indigenous peoples in IR is essential
- A need for capacity building for TK holders to have informed participation in the development of the IR

In the subsequent discussion, it was suggested that intellectual property systems could be used to protect traditional knowledge and that there is a need to find a mechanism that translates traditional knowledge into the commercial realm. There was discussion about the use of customary law. It was also noted that customary law systems, particularly those in Africa, already included components of colonial European law so that there was not a very clear distinction between customary and western law. Others doubted that intellectual property systems could protect traditional law effectively because the system was designed to protect western corporate interests.

It was noted that the protection of traditional knowledge was directly connected to the territorial rights of Indigenous peoples and one could not be protected without the other. Misappropriation of traditional knowledge was less of a problem than the pernicious effects of development.

It was noted that there is a great need for capacity building at the local level to empower traditional knowledge holders and create informed participation by Indigenous peoples in the development of an International Regime. One way of doing this was to include aboriginal representatives in delegations to international negotiations in this area. It was noted that the UN system's unwillingness to recognize aboriginal participation and voting was a barrier. Solutions required full recognition of the right to self government by Indigenous communities.

Indigenous Peoples: Community–level PIC for Accessing Traditional Knowledge and Genetic Resources, Feasibility and Good Practices

Speaker: Brendan Tobin
Paper: Customary Law as the Basis for Prior Informed Consent of Local and Indigenous Communities

This paper seeks to highlight the importance of customary law and practices for the realization of the three objectives of the Convention on Biological Diversity and to help define the modalities for ensuring the effective recognition, respect and enforcement of customary law in any International Regime on ABS. Such regime will have to link together a variety of legal systems and ensure that their consistency and relevancy is recognized. Issues addressed here include: PIC of Indigenous peoples and local communities, searching mechanisms for the protection of TK, building bridges between Indigenous customary law and practice and national and international legal regimes. The paper also addresses the challenge for ongoing processes to elaborate a system for defining ownership and "responsibility" under law in a culturally sensitive and appropriate fashion, without leading to an erosion of confidence and security for communities.

Speaker: Peigi Wilson
Paper: Indigenous and Local Communities: Community-level Prior Informed Consent for Accessing Traditional Knowledge and Genetic Resources

This paper considers various questions regarding ABS and related TK in an effort to reflect common issues of concern raised by various First Nations peoples in Canada. The paper refers to a philosophical difference between the modern perspective where the focus is individualistic, and presupposes human dominance over nature, as opposed to the traditional paradigm based on sustainability, spirituality and seeking human harmony with nature. In the view of the author, the real challenge in the elaboration of an International Regime on ABS will be to ensure that the regime meets the demands of both the modern and traditional paradigms.

Speaker: Paul Kuruk

This presentation explored the concept of prior informed consent as the cornerstone of an International Regime established under the CBD. PIC rules lie in national and regional instruments. There is a need to reflect on the implications of incorporating community-level PIC rules into an International Regime. The African Model Law is an example of legislation that regulates the interface between the collection of biological resources and the recognition of the associated traditional knowledge of Indigenous groups. It is critical that PIC rules incorporated in an International Regime be consistent with the customary law of countries. The assumption underlying the need for compliance with customary law is that it presupposes that customary law is an effective legal system. There is still work to do to ensure that elements of customary law are part of the legal international system and that national customary law is recognized by all countries.

Main issues and concerns

- In PIC discussions at a national level, customary law should be recognized and not be overrided by any other legal system
- There should be certainty in rules regulating access to GR and TK so burden of compliance falls on both users and providers
- Identification of National competent Authority for ensuring PIC by Indigenous communities could facilitate the whole process and give more certainty to all parties
- PIC does not apply only to Indigenous communities but also to other TK holders

In the subsequent discussion, the consistency between western law and customary law when elaborating PIC rules was touched upon. When creating an International Regime on ABS, it is crucial that all countries recognize the existence of customary rules in some countries and that those rules should not be override by any other legal system. Unlike western law, customary law tends to be more uncertain and is oriented towards the resolution of conflicts for the sake of the harmony in the group. It was suggested that views about certainty and uncertainty should be tempered when talking about customary law. It was also brought to discussion that the rules for PIC in some communities are not clear to the members of local communities and that these rules incorporated into an International Regime may seek information that is still unknown by the communities. The discussion about the certainty and uncertainty of the legal system and the rules regulating access to GR and TK must be clear so that compliance does not become burdensome on users only.

Protocols of customary law at the community level should outline the rules of engagement of the parties. This bottom-up approach may be a solution to ensure PIC is given by a community. It was suggested that a competent authority that would ensure compliance with PIC rules should be identified. The identification of a national authority would facilitate the implementation of PIC rules and contribute to the clarification of the rules that need to be observed. The authority could play a role in compiling information about sources of TK, custodians of TK, rights over this knowledge etc. However, it was mentioned that a national authority may have the mandate to give access to land based on PIC but if the community does not recognize this authority, access may be refused. There is a clear need to involve the communities in the decision-making process. It was brought to discussion that the general tendency is to associate PIC with Indigenous communities.

However, it was specified that PIC does not apply only to Indigenous groups but to all groups that have traditional knowledge in various areas such as fisheries and agriculture. The variety of people that use traditional knowledge in their daily activities makes it more difficult to elaborate a system that will engage them all in the elaboration of PIC rules.

Finally, the codification of TK was also at the heart of the discussions. What are the best ways to share TK and clarify the rules for PIC in different countries? Some present believe that codification is not the best way to go, while others think that codification could work but would need to be flexible. It was also noted that not all the TK that is in the public domain was placed there by the communities. Rules within communities sometimes limit the sharing of knowledge between their members. When it comes to redress and legal procedures, it was mentioned that the current legal systems may not be adapted to protecting TK and may lead to encouraging the disclosure of TK. Western legal systems aimed at defending owner's rights may therefore have perverse effects on the protection of TK.

Measures to Ensure Compliance with CBD and Access Legislation

Speaker: Kelly Bannister
Paper: Mechanism for compliance with ABS by the Academic Research Community (Canada)

This paper explains how the scientific community often stands in an interface between providers and users. University scientists are key intermediaries between several different actors. Ethnobiology takes place at the complex interface of ethics and law, governed by institutional research policies that must incorporate evolving sets of ethical and legal standards at the international, national, and local levels. Some Canadian universities and professional associations have developed codes of ethics for conducting genetic research. The paper briefly explores the merits and challenges of existing policies and codes of ethics in Canada. Existing institutional research policies are worth examining as a potential mechanism for incorporating new access and benefit-sharing policy and facilitating compliance with ABS by the academic research community. The existing research policies aim at being consistent with ethics policies for research involving humans and intellectual property ownership policies.

Speaker: Maureen Wolfson
Paper: Scientists as Users and Providers: A South African Perspective

This paper provides a South African perspective of benefit-sharing. The author describes the composition of the Biodiversity Act of South Africa, signed at the end of May 2004. The purpose of the Act is three-fold: 1) regulates bioprospecting, 2) regulates the export of indigenous biological resources, and 3) provides a fair and equitable sharing by stakeholders of benefits arising from bioprospecting involving indigenous biological resources.

Under the Act, permits are required for bioprospecting projects and the export of any indigenous biological resources to be used for bioprospecting and any other kind of research. PIC must be obtained from stakeholders providing access before a permit is issued. When not done for export purposes, research is excluded from the law. Despite the policy vacuum which existed in South Africa (SA) before passing the Act, a number of research organizations have developed policies on ABS. The provincial authorities in the nine different provinces of SA are in different stages of developing policies. However, within government and other institutions, expertise on ABS is deficient which makes it difficult for the government and institutions to develop adequate policies.

Speaker: Joshua Rosenthal
Paper: Measures to Ensure Compliance with CBD and Access Legislation

This presentation focuses on the experience of the International Cooperative Biodiversity Group (ICBG - United States). The ICBG model is presented as a way to encourage companies to follow codes of conduct when conducting research. Codes of conduct are based on ABS principles and IPR protection that must be respected for a research permit to be granted. The ICBG main objective is to change the behavior and attract companies by presenting a range of positive incentives resulting from their good behavior when conducting research. Among other issues, companies will have access to academic expertise, access to unique resources, and share the burden of field and transaction costs, etc.

Main issues and concerns

- Codes of conduct must come as a set of positive incentives for compliance
- Indigenous communities must be further involved in the development of codes of conduct
- Access is key to derive benefits, and scientists contribute to the creation of value for biodiversity
- Further awareness of the issue is needed among scientists and students
- Scientists and students are willing to comply but request regulatory procedures that are simple and flexible
- Public opinion is also something to take into account in codes of conduct

The subsequent discussion started off by a comparison between the activities of botanical gardens and universities. The difference between short versus long-terms projects, access for research or commercial purposes, and dependence on funding from private sectors illustrate how universities and botanical gardens approach to ABS may differ. However, there is a need for those institutions to work together. It was also discussed that codes of conduct must come with a set of positive incentives for compliance.

One intervention was made questioning the involvement and satisfaction of Indigenous peoples in the creation of codes of conduct. In SA, the involvement of such communities in this process tends to increase over years but there is a recognized need for further involvement and input from Indigenous groups.

From a Canadian perspective, it was recognized that there is space for a greater involvement of Indigenous peoples in the creation of the codes of conduct. The experience of the involvement of Indigenous peoples in the elaboration of the codes of conduct of the International Society of Ethnobiology was positive from the scientific side but was is satisfactory for the indigenous communities? This question remains unanswered.

The discussion also reiterated the importance of the work done by scientists in the conservation of biodiversity. There is a need to keep exploring the earth and, as we just scratched the surface, scientists are key in this exercise. The issue of access is therefore at the heart of this process. Access is about talking to people that live on the lands where the resources lie. If no dialogue is established between the users and the providers, no access will be granted and no benefit will be shared.

Acknowledging that structures already exist to encourage scientists to follow codes of conduct when conducting research, there is still efforts to be made to raise awareness among students. Students are often the channels through which genetic material is transferred from a country to another. It is generally recognized that a framework is needed for a better understanding of the underlying rights and duties of ABS both at the research and administrative levels. Students and scientists are willing to comply with the rules but the framework regulating those rules must be simple and flexible enough.

On a practical note, it was mentioned that capacity-building and resources are needed for ensuring that PIC is given in a timely fashion so that research projects are not put on hold for indeterminate periods. It is easier to bypass the law than trying to comply with a system that does not work. Scientists and providers of PIC both share the burden of complying with PIC requirements.

Finally, it was mentioned that public opinion also plays a role in the elaboration of codes of conduct as the general public is becoming highly interested in supporting cautious approaches to research dealing with genetic materials.

IV. Instruments/tools/measures which could assist in achieving the International Regime including Mechanisms for Monitoring and/or Verification

Product and Process Certification Including Certificate of Legal Provenance/ Source/ Origin

Speaker: José Carlos Fernandez
Paper: Elements for the Design of a Certificate of Legal Provenance

This paper makes the case for a certificate of legal provenance as a key instrument to help source countries identify violations to access conditions taking place in other countries with users under their jurisdiction. Such a system could be based upon a number or code attached to all documentation involving a particular genetic resource that could be checked against a central clearing house of certificates available for verification purposes and which would contain the specific conditions for accessing the genetic resource. The paper elaborates on various aspects of such a system by identifying nine key elements and discussing the merits and limitations of the certificate system.

Speaker: Leonard Hirsch
Paper: The Smithsonian Institution: The Life of Natural History Museum Specimens

This paper explains how basic research, collections, and organizations work, and why ABS regulations should be modified to facilitate taxonomic, systematic and ecological research. It describes how burdensome regulatory systems impose costs that far exceed the benefits, and transfer those costs to provider and/or organizations least able to bear them. The paper advocates a mechanism for material exchange that is clear, expeditious and cheap. Material transfer agreements should recognize that museum collections are multi-purpose and differentiate between research and commercialization activities in a dual track system that facilitates basic science and provides for heightened scrutiny and obligations for applied and commercially oriented research. The paper suggests that there could be a Taxonomists Rights principle established by the CBD similar to the Farmers Rights principle in the FAO International Treaty.

Speaker: Brendan Tobin
Paper: Certificates of Origin, Legal Provenance and Source: Mutually Exclusive or Complementary Elements of a Comprehensive Certification Scheme

The paper presents a framework for a system of certification. It focuses primarily on addressing the issues of the subject matter to be certified and what is being certified. A proposal is also made for utilizing certificates as a tool for promoting a more flexible access and benefit-sharing procedure which incorporates elements of both liability and property regimes - as discussed by Ruth Okediji in her conference paper entitled "Access and Benefit-sharing and the Interface with Existing IP Systems: Limits and Opportunities" found in Section III of this publication. The paper lists eight categories of information that could be included in such a certificate. It addresses what should be certified which could include source, origin and or legal provenance and suggests that comprehensive system of certification could accommodate all. It addresses issues of feasibility and cost and key questions for future consideration which include: What should trigger issuing a certificate? Who could issue it? How would multiple source situations work? How could the information be stored? What penalties be levied?, and What would be the system's basic objective? Finally, the paper notes that the results of a UNU-IAS research into this topic will be presented to the Working Group on ABS in February, 2005.

Main issues and concerns

- There is a clear need for a transparent system to administer genetic resources within the IR.
- The concept of a Certificate is very attractive and potentially very useful, but the devil is in the detail
- The certificate could be required for certain types of use, but criteria is needed to define the "triggers"
- There are many things that the Certificate could certify
- One complexity of the Certificate is that it may need to cover not only the biological sample but information also
- Concerns over the lack of a sufficiently well described genetic resource at the point of access
- The consequences of non-compliance, the reduction of transaction costs and the facilitation of research —particularly taxonomic — are all key issues in the design of an effective certificate
- There are problems in extending the Certificate to traditional knowledge, particularly in defining who has the right to issue the Certificate
- The Certificate is a tool, but not a comprehensive solution for a comprehensive and functional IR

In the subsequent discussion, many practical aspects of the potential certificate were raised. It was suggested that a system could not control all transactions involving genetic resources. It was noted, for example, that less than 1 in 1000 Mexican permits for collection of biological material are destined for biotechnology end uses. A feasible system could be based upon the type of use. There was discussion about a "trigger" point i.e. at what point in the research-to-full-commercialization continuum would the holder of a genetic resource be obliged to return to the provider country to discuss benefit-sharing arrangements appropriate to a commercial situation. There was also the basic question of what would a possible certificate certify. Would it be the origin, source country, the movement of the sample, the movement of the knowledge related to the sample, the legal provenance of a genetic resource or some combination of these factors.

In another intervention, it was questioned how a potential certificate would work if it was the information about a genetic resource that was being exchanged rather than the actual sample itself. Another issue raised was how to differentiate between difference species in the same sample which might not leave the provider country jurisdiction and not be investigated and identified for years afterwards. It was suggested that this could be worked out by providing a sample number and then an additional level of numbering system differentiated by species as these were identified.

There was debate on the feasibility of keeping track of many hundreds of thousands of transfers of biological specimens. The task was compared to the international banking system's ability to track millions of financial transactions. It was noted that if the banking system could look after their transactions it should be technically feasible to track a smaller number of biological specimens even if the absolute numbers were still large and the time span for the records might extend out for hundreds of years. It was noted that a banking system is able to pass on the cost of tracking financial transactions to the users themselves and that this might be more difficult for an ABS regime that was looking to facilitate research.

It was noted that the certificate of origin could not easily apply to traditional knowledge until a way of identifying the issuer of a traditional knowledge certificate was developed. It was noted that aspects of the copyright system could be applied to traditional knowledge. It was also noted that researchers derived a reputational and professional benefit from using traditional knowledge in their academic and professional activities. This was a significant benefit even if not part of the conventional definition of commercialization.

The issue of compliance was raised. What would happen if the user did not comply with the terms of a properly identified ABS agreement? The need for a transparent system was underlined.

There was recognition that a certificate of origin was a tool for and not a solution to a functional and comprehensive International Regime. It could be a significant component of such a system if it could be designed so that the costs did not outweigh the benefits. There was recognition that such a system should not impede taxonomical and research activities. It was underlined that the foundation of an International Regime was made up of national legislation on ABS.

Company Conduct, Standards and Certification

Speaker: George Greene
Paper: ABS Management Tool Project: Summary Project Description

The presentation outlines a project to develop and field-test an ABS management tool. Its purpose was to develop collaborative and mutually beneficial relationships between ABS providers and users. It aims to develop a set of substantive practice standards and a management process framework and, at a later stage, consider approaches to assurance (ie from internal review to verification to certification). The potential structure of the tool is described as well as aspects of both a PIC and a community and Indigenous participation practice standard. Once the tool is developed, the study coordinators intend to field test the framework with three pilot studies.

Speaker: Lene Lange
Paper: Tropical Biodiversity, an Industrial Perspective

The presentation outlines Novozyme's development of an internal code of conduct governing ABS. Novozyme is a major European chemical company which uses enzymes (of natural source) for various consumer and industrial products. The guiding principles of the company's benefit-sharing policy include no use of natural products without PIC and disclosure of origin in all research and patents. The presentation described its collaborative relationship with Thailand. Despite its overall positive experience with its own corporate policy, there are several pitfalls. These included: mismatched expectations on the level of royalties potentially available in a low margin industry, the desire of middlemen rather than providers to get the benefits, the practical difficulty of obtaining PIC in many countries, obstacles to scientist-to-scientist collaboration, and poor awareness and implementation of ABS policies in academia. Novozyme will not work in countries nor accept material from *ex situ* collections which have not followed CBD principles on ABS.

Main issues and concerns

- The issue of *ex situ* collections and the extent to which the IR should address it was raised
- An ABS regime should facilitate scientist to scientist collaboration
- There is good potential for win-win collaborative relationships between industry and providers
- There are concerns over the link between benefit-sharing and conservation
- Consultation with Indigenous peoples is imperative for companies whishing to follow best practices

In the subsequent discussion, the need for a potential International Regime to address the availability of *ex situ* culture collections was raised and also the need to develop more *in situ* culture collections. Also an ABS regime should facilitate scientist-to-scientist collaboration. In partial answer to a question whether there were industry-wide codes of conduct, it was noted that US PhRMA members (including both biological and agricultural companies) were intending to release a code of conduct in this area very soon.

It was noted that commercial users of genetic resources should not just take provider country assurances that national ABS policies were being properly followed. These users should look behind the national legislation.

There were questions about the linkages between the ABS management tool and potential linkages to other management tools such as ISO and other systems. There were also questions about the criteria to be employed in selecting pilot project sites and related funding. It was noted that the management tool, once developed, could be a good capacity-building instrument.

It was noted that companies wishing to follow best practices had to consult fully with Indigenous peoples. It was noted that Indigenous peoples had to facilitate consultation for it to be feasible. It was recognized that in the absence of an agreed framework on ABS related to traditional knowledge, at least at the national level, well-meaning companies might avoid using it rather than risk misappropriation. There was a reference to the consultative process developed by oil companies for exploration activities in remote areas and the suggestion that a similar process could be used by PhRMA members.

Five key elements of this discussion were identified: protection of resources might have to come first; there was certainly potential for a win-win collaborative relationship between industry and providers; and an International Regime should have clear objectives and goals; there were many outstanding concerns (e.g, the link between benefit-sharing and conservation, how to control and also facilitate research etc); the need for follow up work on a variety of topics (e.g, certificates of origin, effective codes of conduct, meaningful dialogue with Indigenous communities, the measurement of benefits and the use of other instruments such as trust funds).

Government User Measures

Speaker: Birthe Ivars
Paper: Government User Measures-Incentives for Compliance

This paper provides examples of user country measures taken in Norwegian patent legislation and outside the patent system. It exemplifies the recently amended national patent law in Norway. Among other things, the paper presents the penalties in cases of infringement of the duty to disclose information, as well as the duties to provide information according to patent law. It concludes by addressing traditional knowledge in the legislative process on ABS in Norway.

Speaker: Brendan Tobin

The participant addresses the following question: How to ensure the enforcement of rights embodied in an International Regime on ABS? There is a need to ensure that States will support the protection of the rights of their citizens and will take action to have those rights respected. The rights of Indigenous peoples are not always defended by States and the linkage of the issues under discussion here to broader policy issues would increase the commitment of States to defend the rights of such groups. Many reasons, such as the costs of procedures, legal assistance, and travel expenses, make it difficult for citizens to have a real access to justice. The existence of a special ombudsman office was proposed as a way to respond to claims, help case building, and take action on behalf of groups of citizens. There is a need to reflect more on two specific questions: the enforcement of ABS laws in foreign jurisdictions and the possibility to take action in foreign countries.

Speaker: Christian López-Silva
Paper: User Measures in Provider Countries: Use of Simplified Procedures and Its Trade Implications

The author talks about how most of the attention has been focused on developing regimes to control access, with less attention on promoting compliance by users. The paper explores the possibility of putting in place a measure that would consist of introducing at the national level and within the International Regime a provision that provides for the availability of simplified procedures for nationals of jurisdictions where user measures have been adopted. The identification of such user measures could be done through a database administered by the CBD Secretariat and build upon the information provided by National Competent Authorities. The adoption of these simplified procedures would, according to the author, have the effect of encouraging non-parties to join the CBD and increase compliance with ABS requirements. Many challenges relating to the consistency of the measures taken with the WTO national treatment and most favoured nation principles still need to be addressed. However, the basic principles regulating the relationship between WTO rules and MEAs, CTE analysis and case law may be interpreted as allowing for the development of such measures.

Main issues and concerns

- Many challenges prevent citizens from having effective access to justice to defend their rights related to genetic resources
- Redress and transboundary application of the law are issues that need to be addressed
- Measures included in the law of user countries could to be revised to ensure redress options

In the subsequent discussion, a general agreement was reached that many challenges prevent citizens from gaining real access to justice to defend their rights. The case of Basmati Rice was given as an example whereby the costs, the difference between legal systems (customary vs western law) and the recognition and enforcement of judgements, are some of the challenges that arise when going to court for justice and that developing countries do not have the resources to overcome these barriers and have access to justice. Many interventions were made to the effect that more funds are needed to help citizens from developing countries to take action before the courts. Reference was made to the WTO fund for litigation and proceedings that was set up to help developing countries in accessing justice.

The issue of redress and transboundary application of the law was also greatly discussed. It was highlighted that penalties may drastically vary from country to country. The fact that for similar cases different sanctions from civil to criminal law may be applied, helps contribute to uncertainty. There is a need for a better understanding of The Hague Convention and the transboundary application of law when elaborating an International Regime on ABS. Many subsequent interventions were made regarding the existence of national measures that are not widely shared and the difficulty to have a comprehensive understanding of the measures.

While some people suggested that it is a function of the providers to ensure that the right regime is in place for redress and enforcement, others said that measures included in the law of user countries also need to be revised. One remaining question is about the value added of an International ABS Regime with regards to enforcement of national laws in foreign countries. Current measures included in national law need to be re-assessed to really address this issue. One of the options would lie in the use of administrative remedies. More work should be done to elaborate ways of ensuring redress, such as the removal of licenses, instead of taking action before the courts. Existing structures may offer solutions to stop the abuse of rights that do not necessarily need to be settled before a court of justice.

Finally, some additions were made to the presentation on the Norwegian patent legislation. It was mentioned that the control is outside the patent system. Wrong information purposely provided by an applicant may lead to imprisonment or a heavy fine. Detecting violations and sanctioning depend on the patent examiners and the police authorities and on whether they have the resources to enforce the law. As it stands right now, the legislation does not include any requirement regarding the disclosure of traditional knowledge.

Benefit-sharing as a Goal of the IR (Opportunities, Kinds of Benefits, Successful Experiences, Lessons Learned, Transaction Costs, Limits to Benefit-sharing)

Speaker: Mohamad bin Osman
Paper: Access to Genetic Resources and Benefit-sharing

This paper explores the relationship between ABS, the FAO ITPGRFA treaty, and the CBD. There is a need for a reality check, to acknowledge that the efforts of the negotiations are oriented toward economic benefits. However, to reach economic benefits, countries will have to find solutions to a wide range of ABS related issues such as the need to add value to biological resources, to recognize that corporate investment is crucial for encouraging research, to take into consideration that transaction costs for accessing GR are escalating, and to ensure that the cost/benefits ratio is positive. Many other bottlenecks such as a lack of resources for developing technological capacity are still to be removed. According to the author, importance should be placed on an ABS regime that provides a strong framework for benefit-sharing and provisions for monitoring. The author presents a few examples of projects on BS carried out in Malaysia. In the view of the author, there is a need to look at as many models as possible to learn more about ABS.

Speaker: Preston Scott
Paper: Benefit-Sharing as a Goal of the International Regime: Lessons Learned from Genetic Resources Research at Yellowstone National Park

The paper presents the experience at Yellowstone National Park and how it has gone from a pilot project to a nationwide project. The objectives of the project are three-fold: conserve biodiversity, promote research and generate benefits for biodiversity conservation. These objectives should be met with a minimum of changes to regulations or law. Minimal changes in law would maintain legal certainty, thereby facilitating the involvement of industry and attribution of private-sector funding.

The paper also reflects upon two kinds of interface: 1) the interface between a new IR and national governments (sovereignty), and 2) the interface between access approaches and the mechanics of benefit-sharing which have been mainly contractual so far. These two levels are not mutually exclusive. The papers also states that when developing an International Regime on ABS, the diversity and flexibility of existing approaches should be taken into consideration. Both at the international and national level, we should look at existing structures to address ABS and not create a totally new mechanism. According to the author, there is already an IR on ABS and it is called the CBD. The difficulty to articulate what ABS is about, may come from deeper implementation problems. The current issue that countries are facing is how to improve it and make it work better in a timely fashion. The States have the first responsibility for managing GR and the IR would only be filling a gap.

Speaker: Geoff Burton

The participant reflects on the responsibilities of users and providers, and the importance to look at an international code of ethics for the biotechnology world. Many aspects such as implementation mechanisms, time constraints, credibility of the CBD and the negotiation process, the importance of non-commercial research, existence of non-legal compliance mechanisms such as codes of conduct, certification systems etc., are still pending. More work is needed to confront this reality and address these issues adequately. The authors also states that the industry is not reluctant to benefit-sharing but needs to know the rules and requires more certainty. There is a need to establish a practical dialogue with industry regarding benefit-sharing.

Main issues and concerns

- There is a need to ensure that there is consistency between what is being established within States and the IR.
- The discussion focussed on five areas that were addressed during the workshop. Some of those elements were dedicated a lot of discussion while others are still open for more thoughts from the international community. Future workshops or international talks on ABS should bear the following in mind:
    1) the protection of GR is an investment in the future and the development of future biotechnology applications;
    2) ABS is a window of collaboration between the industry and the providers of GR to ensure that benefits are derived equitably;
    3) any IR should be an enabling institution and be oriented towards capacity-building. It should be strong on benefit-sharing, address adequately the concepts of sovereignty versus international regulation, regulatory versus contractual approach, ensure balance between access rights and rights of providers, and ensure balance between conservation and benefit-sharing. An IR should be simple and tangible;
    4) there are still concerns remaining over the creation of an IR. These include: to ensure effective participation of stakeholders, facilitate corporate governance and recognize the limitations of codes of conduct, the compatibility between a variety of legal systems for enforcement, and the adaptability of countries with no ABS laws and policies, and
    5) future work should bring answers to the role/feasibility of certificates of origin, effectiveness of codes of conduct, fostering of dialogue with industry, measurement of "benefits", the capacity of existing mechanisms to reach ABS objectives, and the creation of funds for conservation.

The interface between an International Regime on ABS and existing ABS regulations and policies was at the heart of the subsequent discussion. There is a need to make sure that an International Regime will be consistent with what is being established within States. The consistency between the two levels of jurisdictions would create an incentive for compliance and would encourage local communities and scientists to participate and comply with ABS policies. One of the remaining questions is whether an IR will facilitate ABS goals in countries that do not have ABS policies or regulations in place.

V. Final Remarks on the Workshop

Co-chairs: Jorge Soberón (CONABIO, Mexico) and Timothy J. Hodges (Environment, Canada)

The two co-chairs thanked the participants for a stimulating discussion and recognized and thanked all the staff who had made the arrangements for the workshop. The co-chairs will be providing their thoughts on the results of the Experts Workshop and the areas needing further work over the next few weeks. This will form the basis of a report to the next meeting of the CBD Open-ended Working Group on ABS, scheduled for February 2005

Annex: Workshop Discussant Papers

The following papers were submitted by those Experts who wanted to express their views about particular issues before and after the Workshop.

Section I: Identification of Outstanding ABS Issues

Access Laws: Challenges in Implementation, Monitoring and Enforcement
by Manuel Ruiz

Access to Genetic Resources and Intellectual Property Rights: What is Biopiracy?
by Stephen Smith

Section II: Vision and Nature of an International Regime: Goals, Challenges, Gaps and the Role of the CBD and other Bodies

International Regime on ABS: Exploring New Options for Achieving CBD-related ABS Objectives
by Stanley S. Atsali

The International Regime – A Missing Element
by Geoff Burton

Nature of an International ABS Regime
by Jock Langford

Towards an International Regime that Stresses Infrastructural Capacity Development in the Source Countries as a Key Factor for Effective Access and Benefit-Sharing in Bioprospecting
by Augustine Bantar Njamnshi

A Few Thoughts on the International Regime and Provider/User Measures
by Nicola Notaro

Section III: Specific Issues for Consideration in the Elaboration of the International Regime

Pharmaceutical Industry Scenarios and Questions Relating to Patent Disclosure
by the European Federation of Pharmaceutical Industry Association (EFPIA)

Biodiversity-based Patent Term Extension: an Opportunity for Using the Existing IP System to Support ABS
by Jock Langford

Intellectual Property Issues: A revision of the current UPOV PVP is required to support the Conservation, Sustainable Development and Benefit-sharing Goals of the CBD
by Stephen Smith

EPRs and the International Regime on Access to Genetic Resources and Benefit-Sharing
by Jesús Vega

A Plant Chemist's Perspective on the "Problem" of Derivatives
by Kelly Bannister

Derivatives
by Geoff Burton

New Forms of Sui Generis Protection Relevant for the International Regime (GR and/or TK)
by Shakeel Bhatti

Lessons for ABS: Academic Policies Community Protocols and Community Level PIC
by Kelly Bannister

The Road to Effective Prior Informed Consent for Accessing the Traditional *Knowledge and Genetic Resources of Indigenous and Local Communities in Colombia*
by Gabriel Ricardo Nemogá Soto

Relevance of Genetic Resources to the Pharmaceutical Industry
by Susan Kling Finston

Access and Benefit-sharing: Role of Scientists
by Jock Langford

"Genetic Resources" and "Utilisation of Genetic Resources": A Legislative View
by Tomme Rosanne Young

Section IV: Instruments/Tools/Measures which could assist in Achieving the International Regime including Mechanisms for Monitoring and/or Verification

Certificate of Origin/Source/Provenance
by Mariana Bellot

ABS Certificate System
by Jock Langford

Uses, Benefits, Tracking and Trade-offs: A Botanical Collections Perspective
by Kathryn Davis

A Simple Solution: Using Certificates of Legal Provenance as a Workable Component of a Functional Regime on ABS
by Tomme Rosanne Young

Company Conduct, Standards and Certification
by Peigi Wilson

Benefit-Sharing as Process
by Kelly Bannister

Benefit-Sharing
by Jock Langford

3. Overall Evaluation of the workshop

Overall Evaluation of the Workshop

At the end of the workshop, all participants where invited to provide feedback on some key aspects of the workshop, including, preparation, organization, content, participation, objectives, management, impact and future steps. In all cases, respondents were asked to rate each different aspect in 5 categories (poor, mixed, average, very good and excellent) and to provide written comments to each of the questions.

There were 27 responses, representing more than half of all experts attending the workshop. In general, participants were also very active in responding in detail, with some nine written comments on average for each question. Below, we provide a general summary of results from the questionnaires received:

1. Preparation

To the question of wheather participants received adequate information on the organization and objectives of the workshop in advance, 21 out of 27 responded that it was very good or excellent, 4 of them thought that it was average and only 1 rated it as mixed.

In the comments section it was noted that information for preparation of outlines proved helpful but the main drawback was that some participants received their invitation in very short notice.

2. Organization

Two questions under this heading: was the workshop well organized (logistics)? and, were the workshop facilities and accommodation suitable?

On the first question, 17 participants consider the organization excellent and the remaining 10 very good.

On the second question, the responses were virtually the same (17 excellent, 9 very good), but one participant considered that the facilities and accommodation were average.

3. Overall content

Regarding the relevance of the content of the workshop to the area of work/need of the participants, 14 consider the workshop excellent, 12 very good and one average. As to wheather the workshop reflected leading thinking on ABS, 14 consider the workshop excellent, 10 very good, one average, one mixed and one.

Some of the comments recommended that a greater attention to indigenous issues was needed. The agenda was too wide for some, but most comments agreed that the main issues related to the IR were covered.

4. Participation

All but two participants considered that they had an excellent (11) or very good (14) opportunity to contribute their views to the workshop, only two participants consider the opportunity as average.

Some participants felt that the workshop could have benefited from small group discussions and others welcomed the idea of short papers and the absence of introductory presentations to allow for more discussion time.

5. Achievement of objectives

This section received the lowest scores from the participants viewpoint. There were two questions in this section, asking wheather the objectives were clearly communicated and if they were achieved.

On the first question, only 6 participants considered that the communication of the objectives was excellent, 16 as very good, 4 as average and 1 as mixed. Perhaps it is for this reason that the distribution of responses to the second question were very similar: only 3 consider that the objectives were achieved with excellence, 16 very well, 5 average and 3 mixed.

Some comments stated that it is too early to assess wheather the objectived were achieved. One participant commented that the scope was too broad. Others stated that they would have liked to have reached more concrete conclusions on the elements and points for the IR.

6. Overall management

The workshop's overall management was highly graded, with 11 participants consider it excellent, 14 as very good and only 2 as average.

The comments in this section provided several concrete proposals for improvement, from time control for presenters, the use of summaries and the linkage of issues under consideration.

7. Impact

On impact, most participants rated the workshop as excellent (10) or very good (14) with only one participant rating it as average. The comments dwelled on the future challenges of disseminating the results of the workshop to ensure that they are used.

8. Future steps

Under this heading, no rating was requested, but 12 participants provided feedback. Some of the main ideas included,

- Another workshop between the 2 next working group meetings.
- A workshop for indigenous peoples
- Ensure dissemination of outcomes

4. Experts' Papers

Section I: Identification of Outstanding ABS Issues

A: Level of National Implementation

National Implementation

Valérie Normand[1]. Programme Officer, Access and Benefit-sharing, Secretariat of the Convention on Biological Diversity. E-mail: valerie.normand@biodiv.org

Some facts

National Focal Points and Competent National Authorities

Parties were requested by the Conference of the Parties —at COP-5 in April 2000 (decision V/26A)— to designate a national focal point and one or more competent national authorities, as appropriate, to be responsible for access and benefit-sharing (ABS) arrangements or to provide information on such arrangements in their jurisdiction. As of 20 October 2004:

- 42 countries had nominated national focal points on ABS (http://www.biodiv.org/doc/lists/nfp-abs.pdf)
- 14 countries had nominated competent national authorities for ABS (http://www.biodiv.org/doc/lists/nfp-abs-cna.pdf)

Access and Benefit-sharing Measures

COP-6, in 2002, requested Parties to make available to the Executive Secretary "detailed information on the measures adopted to implement access and benefit-sharing, including the text of any legislation or other measures developed to regulate access and benefit-sharing" (decision VI/24D). The Executive Secretary was requested to compile the information received and to make it available through the Clearing House Mechanism in order to facilitate access to this information by Parties and relevant stakeholders.

A database on access and benefit-sharing measures was established and can be accessed through the Clearing House Mechanism at the following address: http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx. It includes national or regional strategies, policies, legislations and regulations dealing with access and benefit-sharing developed in 3 regions (the Andean Community decisions, the draft Central American Agreement and the African Model Law) and 26 countries. Only measures available from official sources were included in the database. In a majority of cases, the source of information is a government website.

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[1] The views expressed in this paper are those of the author and do not necessarily represent the views of the Secretariat of the Convention on Biological Diversity

These countries are at different levels of implementation of access and benefit-sharing and have adopted different approaches to regulating ABS, reflecting their national administrative structures, priorities, cultural and social specificities. While certain countries have only adopted one measure, generally legislation, others have adopted a package of measures including, for example, a national strategy, legislation and regulations or guidelines. A number of countries are still in the process of developing their national systems and therefore the package is often incomplete (e.g. a number of countries are in the process of developing ABS guidelines or regulations to complement legislation dealing with access and benefit-sharing). In addition, the national procedures and structures are diverse. For example, some countries have different levels of government responsible for regulating ABS —at a national/federal or state/provincial level.

In a number of countries, general legislation on environment, sustainable development and biodiversity issues address access and benefit-sharing in more or less detail and provide for the establishment of guidelines or regulations. Some of these guidelines or regulations have already been adopted (e.g. Costa Rica, India, Malawi), whilst others are in draft form (e.g. Australia, Philippines) or still to be developed (e.g. Bulgaria, Gambia, Kenya, Peru, Uganda, Venezuela).

A majority of the countries with national measures included in the CBD database can be divided into three categories:

The first category includes countries which refer to access and benefit-sharing in their national biodiversity strategy or their environmental or biodiversity legislation but have not yet regulated ABS in any detail. These measures generally provide for the development of ABS regulations and include some general specifications regarding elements to be addressed by the regulation. Countries in this category include Argentina, Cameroon, Cuba, Gambia, Kenya, Panama and Uganda.

The second category includes countries that have biodiversity or environmental legislation with some general provisions on access to genetic resources or biological resources, which may include a provision for the establishment of a regulation on ABS. The countries included in this category are Bulgaria, Ecuador, Mexico and Nicaragua.

The countries in the third category are those which have addressed ABS in greater detail, including Australia, Bolivia, Brazil, Colombia, Costa Rica, Guyana, India, Malawi, Philippines, Peru, South Africa, Vanuatu and Venezuela. They have established competent national authorities, procedures for prior informed consent, procedures for the development of mutually agreed terms, including benefit-sharing, and compliance measures. The issue of intellectual property rights is also generally addressed in various manners and in varying degrees of detail. Although the provisions developed to address these elements vary, from one national system to another, some general underlying trends may be highlighted:

Competent national authorities

In some cases, the competent national authority is an organization already in existence, while in other cases a new organization is created through the establishment of the ABS measures.

Prior informed consent

In each country, some type of application for access has to be made in order to obtain access to genetic resources. These provisions also provide guidelines on the specific information an application should contain and the procedure leading to approval or refusal. The approval or refusal to grant access is determined by the competent national authority. A majority of the measures examined also require the prior informed consent of the relevant authority/resource provider in the geographical area where the genetic resources are to be accessed. Specificities of some measures include different requirements for access depending on the type of applicant (e.g. national or foreigner) and different requirements depending on whether access is granted for commercial or non-commercial purposes. In some countries, a certificate is issued once prior informed consent has been obtained or for permission to export.

Mutually agreed terms

A majority of existing national systems provide that mutually agreed terms are to be set out in an agreement. Some measures also provide for different types of agreements depending on whether the genetic resources are being accessed for research or commercial purposes. The measures generally provide that the agreement is to be approved by the competent national authority. Measures also generally provide for benefit-sharing with the competent national authority, or with indigenous and local communities or other resource providers, and in most cases for both. Indications regarding the types of benefits to be shared vary depending on the measures.

Compliance measures

The measures examined generally include provisions dealing with compliance. Although few specifically address monitoring and enforcement to ensure compliance with ABS measures, they generally provide penalties/sanctions for infractions or offences, such as a failure to adhere to set legislation, regulations or guidelines, unauthorized access and the non-respect of the clauses of an ABS agreement. These sanctions include fines, seizure of samples, revocation/cancellation of the permission to access, revocation of the agreement, a ban on future bioprospecting, and imprisonment.

The information contained in the database is incomplete. Additional initiatives have been undertaken by countries to address ABS. Some of these initiatives are measures which have been adopted even though the official text of the measure has not been made available. In other cases, the mechanisms used to address access and benefit-sharing have not been reflected in a specific measure, rather existing legislative or regulatory frameworks developed for specific sectors, such as protected areas or forests, have been adapted to respond to ABS situations.

It is difficult to draw general conclusions from the analysis of these measures. Countries are at different levels of development and have varying levels of capacity to deal with access and benefit-sharing issues and consequently have adopted different national approaches. There is a need to assess existing experiences with ABS implementation, however limited information is available.

Implementation of the Bonn Guidelines

At COP VII (in decision VII/19), Parties and all relevant stakeholders were encouraged to provide information on relevant experiences and lessons learned from implementation of the Guidelines. The CBD Secretariat has received information from few countries regarding national initiatives to implement the Bonn Guidelines. These countries are largely users of genetic resources.

The initiatives reported on, generally focus on raising awareness to access and benefit-sharing among stakeholders and consequently creating national capacity to address these issues. These initiatives have included:

- Awareness raising through campaigns and workshops with relevant national stakeholders and potential users of genetic resources on access and benefit-sharing issues and the development of national ABS policies;

- Information gathering and exchange through national studies to identify the level of awareness to access and benefit-sharing issues among stakeholders, in order to determine for example whether stakeholders are using the Bonn Guidelines in order to encourage the implementation of access and benefit-sharing requirements;

- The development of codes of conducts or guidelines for users of genetic resources under their jurisdiction, such as researchers and *ex situ* collection holders;
- The establishment of ABS requirements as prerequisites for publicly funded research;
- Amendments to national patent legislations to include the disclosure of origin of genetic resources and associated traditional knowledge as a requirement in patent applications where the invention is based on a genetic resource and associated traditional knowledge.

Capacity-building related to Access and Benefit-sharing

At COP VI (decision VI/24), Parties, indigenous and local communities, relevant inter-governmental organizations, non-governmental organizations and the private sector were invited to provide information to the Executive Secretary on existing initiatives and activities for capacity-building for access and benefit-sharing. At COP 7 (decision VII/19F) the Action Plan on Capacity-building for access and benefit-sharing was adopted and Parties were requested to make information available about their implementation of capacity-building measures.

Following COP VI, a database on capacity-building projects for access and benefit-sharing was established to facilitate information-exchange on ongoing capacity-building activities and this is available at: http://www.biodiv.org/programmes/socio-eco/benefit/projects.aspx. The database includes information on various ongoing capacity building projects related to access to genetic resources and benefit-sharing. Each entry contains basic information about each project, including: its status, countries or regions covered by the project, the lead organization(s) and contacts, funding details, objectives and activities, outcomes and lessons learned.

The database is being regularly updated on the basis of information provided by Parties and relevant organizations which have been involved in capacity-building activities. It currently contains information on 17 capacity-building projects.

A number of projects are aimed at creating awareness to access and benefit-sharing issues and at developing capacities to assist countries in negotiating an international ABS regime and in the development of national access and benefit-sharing systems and their implementation.

Challenges

Developments are currently taking place in a number of countries, through national initiatives and capacity-building projects. There is, however, still a lack of awareness and capacity to address access and benefit-sharing among relevant actors, in both developed and developing countries. In addition, a number of countries have yet to develop specific ABS measures. Under these circumstances:

- How to further contribute to awareness raising among relevant stakeholders with respect to ABS issues?
- How to contribute and facilitate information exchange with respect to ABS developments?
- What additional steps could be taken to encourage the implementation of the Action Plan on capacity-building for ABS?
- How to further benefit from the experiences of countries in the development and implementation of national ABS systems?
- Should a certain level of harmonization among national ABS systems be encouraged?
- How can compliance with ABS requirements of provider countries be ensured once the genetic resources accessed have left the provider country?

Section I

B: National Access Laws (Challenges), Continuing monitoring and enforcement Issues

The Challenges in the Implementation of the Philippine ABS Regulations: Monitoring and Enforcement of Bioprospecting Activities in the Philippines

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Access and Benefit-sharing (ABS) Regulations in the Philippines

In 1995, *Executive Order No. 247* was issued as the Philippine's response to the call of the Convention on Biological Diversity (CBD) for signatories to take appropriate measures to ensure that countries providing genetic resources are given access to and transfer of technology that uses those resources, on mutually agreed terms.

On 30 July 2001, the Philippine Legislature enacted the *Wildlife Resources Conservation and Protection Act* which has repealed by implication, or amended accordingly, EO 247.[1] Provisions in the EO, which are clearly contradictory to and irreconcilable with the Wildlife Act, are now deemed repealed.[2] A new set of implementing guidelines on bioprospecting, issued pursuant to the Wildlife Act and other relevant laws, is almost in its final stage of formulation.

Challenges in Implementation of Philippine ABS Regulations

During the time that EO 247 was effective, there were several issues that in some way affected the full implementation of the law. These are as follows:[3]

- The scope of the EO is too broad. As defined "bioprospecting" appears to cover all kinds of collection, research, and utilization of biological and genetic resources, including conservation research which have nothing to do with prospecting. It is also ambiguous as far as *ex situ* collections are concerned;
- The process is cumbersome, costly, and considered a deterrent to research growth and development;

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[1] The repealing clause provides "Act Nos. 2590 and 3983, Commonwealth Act No. 63, as amended, Presidential Decree No. 1219, as amended, Republic Act No. 6147, and other laws, orders and regulations inconsistent herewith are hereby repealed or amended accordingly."

[2] There are two categories of repeals by implication. The first is where provisions in the two acts on the same subject matter are in irreconcilable conflict, the later act, to the extent of the conflict, constitutes an implied repeal of the earlier one. The second is if the later act covers the whole subject of the earlier one and is clearly intended as a substitute, it will operate similarly to a repeal of the earlier act (Agpalo 1990).

[3] In 1998, the Southeast Asia Regional Institute for Community Education sponsored a series of seminars/workshops to review/assess the EO. Various stakeholders participated in these workshops where issues and concerns affecting the implementation of the EO were identified and solutions/recommendations were formulated. The results were later transmitted to the IACBGR.

- The PIC requirement is administratively tedious and burdensome, especially the 60-day waiting period before PIC is issued. Most collectors also dread the PIC requirement due to economic costs. Identifying which community should give consent is often problematic, especially in the case of pelagic or migratory species;
- An inter-agency approach has many inherent problems such as difficulty in getting a quorum of the members, irregular attendance of members, and the problem of coordination. In addition, responsibilities of the member agencies are not clearly delineated;
- There is no specific source of funds provided, except of those from the savings of the concerned government agencies and the fees collected by the Inter-Agency Committee on Biological and Genetic Resources (IACBGR);
- Local scientists view the benefit-sharing requirements under the EO as too demanding while others believe that the benefit-sharing provisions do not go far enough. Other questions posed which they feel should be answered include: How do we ensure equitable sharing, who should get what, how much, and for how long, what are the forms of benefit-sharing, and will the community benefit? etc. Some believe that the community should be given a bigger role in negotiating benefit-sharing (Peria 1998);
- Effective bargaining and negotiation have not been given serious consideration, and
- The EO does not provide for a mechanism to ensure that its goal to protect and conserve biological and genetic resources is being achieved. There is no financing mechanism or trust fund in place to support biodiversity conservation objectives (Ochave 1999).

The Wildlife Act and its proposed implementing rules and regulations attempt to address most of these issues and concerns by providing the following:

- Bioprospecting for purposes of scientific or academic research is no longer subject to the requirements of the law for commercial bioprospecting;[4]
- Its proposed implementing guidelines categorically states that it covers wildlife, microorganisms, domesticated or propagated species, exotic species and all *ex situ* collections sourced from the Philippines except those currently accessed under international agreements where the Philippines is a party;[5]
- No inter-agency body to implement. The Secretary or its representative, in consultation with the concerned agencies, signs the Bioprospecting Undertaking (BU) which authorizes a bioprospector to undertake bioprospecting activities. However, consultations with concerned agencies are still necessary before any grant for bioprospecting is allowed;[6]
- Prior informed consent from concerned IPs, local communities, PAMB, or private individual entities is still required in accordance with existing laws, but the 60-day requirement, which has been widely criticized, has been removed;[7]
- In case the applicant is a foreign entity or individual, a local institution shall actively participate in the research, collection, and if applicable and appropriate, in the technological development of the products derived from the resources;[8]

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[4] Sec. 14 & 15 in relation to definition of "bioprospecting", RA 9147.

[5] Sec. 2, 2.1, Proposed Guidelines on Bioprospecting Activities in the Philippines

[6] Sec. 14, RA 9147

[7] Ibid.

[8] Ibid.

- A wildlife management fund is created that shall finance the rehabilitation or restoration of habitats affected by acts committed in violation of the law, as well as support scientific research, enforcement and monitoring activities, and the enhancement of capabilities of relevant agencies;[9]
- Unauthorized collection, hunting and possession of wildlife is punishable with imprisonment of up to four (4) years and a fine of up to P300,000 depending on the species illegally collected, hunted, or being held.[10] The law, however, is silent on the liability of a person caught bioprospecting illegally;
- The minimum terms and conditions found in the EO were not legislated. Rather, the Secretary is given the option to impose reasonable terms and conditions which are necessary to protect biodiversity. This gives the Secretary of said agencies great flexibility in the conditions to be imposed;[11]
- Equitable sharing of benefits derived from the utilization of biological and genetic resources is not mentioned in the law but is incorporated in the proposed implementing guidelines,[12] and
- The proposed implementing guidelines also provide for a simplified process for securing Bioprospecting Undertaking.[13]

Monitoring and Enforcement of Bioprospecting Activities

Implementing agencies monitor compliance with the processes involved and conditions attached to the BU. Also, monitoring includes not only activities of the authorized resource users but those illegally using the resources for bioprospecting purposes. Furthermore, monitoring involves activities both within and outside Philippine territory.

Under the EO, the respective member agencies of the IACBGR shall conduct monitoring of research agreements based on a standard monitoring scheme to be devised by the IACBGR for that purpose.[14] There shall be an IACBGR monitoring team responsible for establishing a mechanism to ensure the integration and dissemination of the information generated from research, collection, and utilization activities.[15] Another monitoring team, headed by representatives from the Department of Science and Technology (DOST) and the Department of Foreign Affairs (DFA), shall monitor the progress of research, utilization, and commercialization outside the country.[16] All these provisions were never enforced. The implementing agency relied heavily on reports submitted by the resource user and a representative accompanying the resource user during PIC and BS negotiation and collection of samples.

Nevertheless, pursuant to other rules and regulations, the Department of Environment and Natural Resources (DENR) requires a permit for the transport of wildlife from one place to another within the country as well as export permit for transport outside the Philippines. This permit system aims to prevent collection of resources without the required official authorization.

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[9] Sec. 29, RA 9147

[10] Sec. 27 (f) and Sec. 28, RA 9147.

[11] Sec. 14, RA 9147

[12] Chapter VI, Proposed Guidelines on Bioprospecting Activities in the Philippines

[13] Chapter III, Proposed Guidelines on Bioprospecting Activities in the Philippines

[14] Sec. 12 (12.1), DAO 96-20

[15] Sec. 12 (12.2). DAO 96-20

[16] Sec. 12 (12.3), DAO 96-20

The Wildlife Act does not provide for a specific provision on monitoring bioprospecting activities but the transport and export permitting system continues and violators are penalized. However, one of the objectives of the proposed *Guidelines on Bioprospecting Activities in the Philippines*, the Act's implementing guidelines, is to establish a cost-effective, efficient, transparent and standardized system for monitoring compliance with the provisions on PIC; collection quota; fair and equitable BS; transfer of materials to third party and other provisions of the BU. It provides for the following:

- an annual progress report is submitted by the resource user containing the current status of the procurement of PIC, progress of collection of samples, benefit sharing negotiations and progress on payment of benefits or other provisions of the BU;
- certification is issued by the resource user and provider that there has been proper procurement of PIC, acceptance by resource providers of benefits, compliance to collection quota;
- a checklist of process and content indicators is provided, and
- a monitoring team is created.[17]

For overseas monitoring, the assistance of the DFA and DOST in monitoring inventions and commercialization in foreign countries shall be sought. In particular, the DFA is encouraged to work with concerned foreign authorities on the following aspects: a) prevention of biological resources from entering countries without a BU; b) requirement for disclosure of country of origin and presentation of BU in patent applications; and c) facilitation of enforcement of claims against collectors or commercializing entities. The DFA and DOST are encouraged to establish and maintain ties with firms that have BUs with the Philippines as well as with professional societies and universities that deal with the use of Philippine biological resources.[18] Furthermore, civil society participation is highly encouraged in monitoring compliance with the BU.

Since 1995, we have only one Commercial Research Agreement (CRA) and one Academic Research Agreement (ARA) that have been processed under EO 247. There is another CRA granted by the Department of Agriculture but it did not pass the process under EO 247. As mentioned there is no concrete and specific monitoring scheme designed under EO 247. Monitoring of these agreements has been based only on the annual progress reports submitted by resource users and the implementation of the transport and export permitting system. There is also no clear and effective mechanism that deals with monitoring and enforcement of Philippine biological resources brought out of the Philippines. How to enforce negotiated benefits outside the Philippines remain unanswered.

As presented above, the EO has been affected by such a number of issues that its full implementation suffered greatly. The implementing agency concerned itself more with determining what are activities should be covered, how to deal with local scientists and researchers, and how to streamline the process, etc. that monitoring and enforcement were relegated to the background. Also, there were no agreements reached on monitoring and the transport and export permitting system seemed adequate at that time. A lack of financial and human resources also contributed to weakened monitoring and enforcement activities.

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[17] Sec. 24 and 25, Proposed Guidelines on Bioprospecting Activities in the Philippines

[18] Sec. 26, Proposed Guidelines on Bioprospecting Activities in the Philippines

The Wildlife Act, through the proposed guidelines, will attempt to establish a better monitoring and enforcement system. The questions, however, remain the same: Will the monitoring guidelines under the proposed regulations work this time? Are they sufficient to monitor and enforce the provisions of the law and the agreements outside Philippine territory? Can we really enforce our agreements outside our country? Where do we go if violations are committed by the foreign resource user? We are still grappling for answers.

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National Access Laws: Challenges, Benefit-sharing, Monitoring and Enforcement

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Introduction

Countries with federal structures of government face very specific challenges when introducing national access laws. Australia is a good case study of those challenges. Its challenges and solutions found may be of interest to other countries dealing with similar issues. Some issues are common whether or not a federal structure exists.

Australia has adopted a pragmatic approach to implementing the CBD's Bonn Guidelines. This approach is guided by the needs of a federal structure, the realities of contemporary scientific research and its market-based, developed economy with a strong stakeholder voice in decision making. This approach is encapsulated in its intergovernmental agreement titled the *Nationally Consistent Approach for Access to and Utilization of Australia's Native Genetic and Biochemical Resources (NCA).*[2] All 9 Australian governments agreed to this overarching policy on 11 October 2002 to form the basis for Australia's implementation of the Bonn Guidelines. The agreement forms an accountable basis for all legislation and administrative action for the management of genetic resources currently underway in each Australian jurisdiction.[3]

Challenges

Federalism, Land Management and Consensus

Australia is made up of 6 sovereign States and two self-governing Territories. Under Australian constitution, land management responsibility largely rests with the States. Historically, achieving a common view among all sovereign jurisdictions has not always been easy and land management issues are a current source of acrimonious and divisive debate on such matters land clearing, salinity and allocation of riverine water resources. Australia has a small population (20 million) spread over a wide area: its lands and seas extend from the tropics to the Antarctic with more than 8 million square kilometers of land and it has a marine area of similar size. Accordingly, views on land management issues are often entrenched at the state level. A primary tool for addressing such divisions has been the creation of the Council of Australian Governments (COAG) and the Natural Resources Management Ministerial Council.

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[1] The Views expressed in this paper are those of the author and do not necessarily present those of the Australian Department of the Environment and Heritage.

[2] See URL: http://www.deh.gov.au/biodiversity/science/access/nca

[3] Such action was foreshowed at Objective 2.8 of the 1996 *National Strategy for the Conservation of Australia's Biological Diversity*. See URL: http://www.deh.gov.au/biodiversity/publications/strategy/

The twin drivers for successful coordination and co-operation between Australian governments on the ABS issue and leading to the adoption of the nationally consistent approach were awareness of:

- The extent of national biodiversity;
- The value genetic resources to industry worldwide,[4] and
- Jurisdictions' obligations under the CBD.

Australia is one of 17 megadiverse countries. It is estimated to have up to 7-10% of the world's biodiversity, perhaps less than Indonesia or Brazil but comparable to Mexico.[5] Australia has the world's highest rate of endemism.[6] Much of its biodiversity is also unusual, ancient, rare or inadequately known to science.

Australia is a developed country with a good science base and a burgeoning biotechnology industry with an annual turnover of more than US$750 Million.[7] Of its 198 biotechnology firms, most are small and are constrained by a conservative capital market and a poor record of successful commercialization. Australian biotechnology research and development has its foundations in medical research, agriculture and natural product discovery.

The mechanism chosen by the federal government to increase awareness and to begin to build a consensus was to hold a national inquiry[8] involving extensive stakeholder consultation. This involved all governments, indigenous peoples, industry, the science community and environmental groups. The process identified key problems and suggested solutions. By clarifying thinking within government on ABS, Australia was able to give informed consideration to the draft Bonn Guidelines and was thereby encouraged to strongly support their adoption.

Implementation - National Consistency

In a federal structure, a coherent legal framework requires either a single national law (not always possible), "mirror" or "model" legislation —where each jurisdiction passes essentially the same law— or a law based on an agreed nationally consistent approach. In Australia the complexities of ABS and existing State or Territory laws and State constitutions led to the adoption of the third option. This is the *Nationally Consistent Approach for Access to and Utilization of Australia's Native Genetic and Biochemical Resources*, or NCA.

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[4] For example Laird and Ten Kate quote the 1998 annual sales value of pharmaceutical products derived from genetic resources as being US$75 billion - *Biodiversity and Traditional Knowledge*, p247, edited by Sarah Laird and published by Earthscan Publications Ltd, 2002.

[5] Mittermeyer.

[6] Laird and Ten Kate *op. cit.* Estimates of biodiversity within national jurisdictions vary depending on the assumptions used and the proportion of the nation's biodiversity taxonomically identified and mapped. In Australia's case a significant proportion of its biodiversity, particularly in its marine sphere, remains to be identified. A further complication is that fact that from a biodiscovery point of view the degree of polymorphism within a species can be as important as the number of species evident.

[7] Australian Government Department of Industry Tourism and Regional Services -figures for 2003.

[8] Commonwealth Public Inquiry into *Access to Biological Resources in Commonwealth Areas 2000 (the Voumard Inquiry)* see URL: http://www.deh.gov.au/biodiversity/science/access/inquiry/pubs/abrca.pdf

The NCA identifies key problems and agreed solutions. Its common goal is "to position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital".[9] At the time of writing, most Australian governments have begun policy reviews, passed legislation or commenced preparation of new legislation under the aegis of the NCA.[10]

Realistic Expectations - the Success Rate

Stakeholders repeatedly emphasize that the chances of a new product based on natural genetic resources reaching the market is very low: about 1 in 10,000 to 1 in 100,000. Furthermore many discoveries are serendipitous and the development process is often cumulative, expensive and lengthy. While some products may be very valuable in the end, they are the exception.[11] Even at the final stages of the development process there are no guarantees. For example it is estimated that only 20% of new pharmaceutical drugs that undergo Phase 1 clinical trials will survive to be approved by the USFDA.[12] Policy, legislation and public education activities must take this reality into account.

The immediate implication of such low success rates for development from biodiscovery is that bioprospecting as an activity is sensitive to transaction costs, both financial and temporal (delay). This sensitivity is further exacerbated where research is undertaken by small organizations (often the Australian case) or is undertaken as non-commercial research. In such circumstances, burdensome regulatory impediments will reduce research thus further reducing the likelihood of success. Regulatory impediments include:

- cost
- delay
- uncertainty
- duplication
- complexity

The lesson Australia learned from observing the effectiveness of early ABS legislation in South America and in the Philippines is that such impediments are to be avoided. The appropriate response is to balance safeguarding the public interest with arrangements facilitating access by the following:

Simplicity

Keep the underlying organizing principle simple. For example, for access to be granted on federal land an applicant must apply for a permit, the permit in turn will be granted if the collecting does no harm to the environment and a benefit-sharing agreement has been reached with the manager of the area from which the resources are to be taken. If the collection is for non-commercial purposes the benefit-sharing agreement may be replaced with simplified arrangements.

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[9] See URL: http://www.deh.gov.au/biodiversity/science/access/nca/#goal

[10] The federal government has drafted legislation for areas under its control. The Queensland Biodiscovery Bill was passed in August 2004, In September 2004 Northern Territory released its ABS policy for public comment while South Australia is preparing legislation and Western Australia has announced its intention to draft legislations.

[11] E.g. 1997 sales revenue for Cyclosporin based products amounted to US$1.2 billion These were developed from a soil fungus found in a sample taken from a nature reserve in what is now Norway's Hardangervidda National Park, but the process took 14 years and considerable cost. - Pp 163-4, Biodiversity and Traditional Knowledge, Edited by Sarah Laird and published by Earthscan Publications Ltd 2002.

[12] Journal Of Commercial Biotechnology Sept 2003 Vol 10 Number 1, page 55.

Reducing costs and delay

The NCA provides for:

- processing of applications for access to be timely (eg federal and state legislation includes statutory time limits for decision making);
- transaction costs to be minimized (eg draft federal legislation fixes fees at nominal levels);
- model contracts and dictionaries of contractual terms for benefit-sharing agreements to be developed;
- information to be provided in a clear, readily-accessible and reliable manner;
- reassurance to be provided that arrangements do not alter existing property or intellectual property law (this is reflected in federal and state law;
- access permissions to allow flexibility in their scope and duration; and
- online application processing and information provision be used where possible.[13]

Ownership of resources

Generally, genetic resources found on public lands or waters are either owned or managed by government bodies. Nevertheless the NCA identifies this as a matter requiring further collaboration, particularly the possible application of frameworks to private land. The new Queensland Act does not regulate the use of genetic resources on private land (including indigenously owned land) while both federal and Northern Territory governments have made clear that they will respect the property rights of private land holders. The property rights of the owners of indigenous owned land in federal areas is explicitly protected in the draft legislation.[14] All benefits negotiated by them are theirs. The federal government takes none. Guiding this debate is the realization that the conservation of the bulk of Australia's biodiversity will take place within its extensive representative protected areas system i.e. mostly within public areas.

Avoiding duplication of existing systems

Under the NCA, regulatory frameworks would allow for possible exemption of public collections administered consistently with its Principles. This might include, for example, institutions such as botanic gardens or herbaria that are participating institutions in the international Common Policy Guidelines for implementation of the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions". The goals here are not to duplicate existing arrangements if they are consistent with the intent of the policy.

Such provisions are especially necessary where systems are in place to discharge obligations under other international obligations or where a state may have been granted control over resources under another federal law.[15] In the latter instance federal policy is that the arrangement should remain undisturbed, as any benefit received by a State is a benefit to the broader Australian community. The Commonwealth State Offshore Constitutional Settlement is an example of such an arrangement.

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[13] See NCA Common Element 3

[14] This is done, in part by access approval to be given when the applicant demonstrates that the informed consent to the benefit-sharing agreement by the indigenous owners.

Certainty

The Australian experience has been that stakeholders place great value on certainty. To build this into legislation and administration the NCA ensures that transparency and accountability is to be supported by:

- legislation;
- disclosure of all criteria against which access is granted;
- appropriate integration of decision making into administrative review systems; and
- making information about benefit-sharing agreements public, where doing so is consistent with commercial, privacy and cultural confidentiality.

Ease of access and administrative consistency across all jurisdictions

This is supported by the undertaking in the NCA to collaborate on:

- the use of common terms wherever possible;
- agreement on appropriate deterrent penalty levels for similar offences;
- the development of model contracts and contractual terms;
- establishing links between web based on-line information sites;
- developing consistent public information material;
- the use of joint benefit-sharing contracts where intended biodiscovery collection involves crossing jurisdictional borders;
- the adoption of common collection protocols where possible;
- the sharing of common experience;
- the development of whole of government policy positions in relevant international fora;
- common issues such as the ownership of resources and the possible application of frameworks to private land, and
- the development of contract monitoring and access compliance procedures.

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[15] Such an exemption might be framed along the following terms: "The Minister may declare that this Part does not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection) if: (i) the resources are held as specimens away from their natural environment (whether in a collection or otherwise) by a Commonwealth Department or Commonwealth agency and there are reasonable grounds to believe that access to the biological resources is administered by the Department or agency in a manner that is consistent with the purpose of this Part; or (ii) there are reasonable grounds to believe that access to the resources is controlled by another Commonwealth, self-governing Territory or State law in a manner that is consistent with the purpose of this Part; or (iii) use of the resources is required to be controlled under any international agreement to which Australia is a party." *Example*: The International Treaty on Plant Genetic Resources For Food and Agriculture, to which Australia is a signatory, obliges signatories to "control access to the genetic resources of some foods in some circumstances".

Fair treatment

Industry representative bodies including the International Chamber of Commerce have emphasized the concern of members, particular those from outside Australia that Australia's system not discriminate against their members. This is a larger trade concern and is addressed by existing legislation which makes such action unlawful and which binds the States and Territories. Accordingly the NCA makes reference to National Competition Policy and the *Trade Practices Act 1974*.

Unintended regulatory consequences

The scientific community has sought to draw governments' attention to the risk that non-commercial research may be adversely affected by arrangements intended to regulate commercial research. To address this the NCA requires that all jurisdictions facilitate continued access for non-commercial scientific research, particularly taxonomic research. In the case of the federal legislation a clear distinction is made between commercial and non-commercial research.[16]

Respecting Indigenous Knowledge

While the NCA requires that all governments "recognise the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms" it leaves the method to individual Australian Governments. The federal government employs the use of transparency. It requires that a benefit-sharing agreement includes protection for, and recognition of and the valuing of, any indigenous people's knowledge used. The agreement must also include a statement regarding the use of indigenous people's knowledge and provide details of the source of the knowledge, the terms on which it was obtained and benefits to be provided or any agreed commitments given in return for its use.

Negotiation disparities

To the extent that benefit-sharing agreements are negotiated between government entities and research organisations or companies there is no disparity. Where the managers or owners of the genetic resources are Indigenous peoples this is not the case. Accordingly federal legislation provides a safeguard whereby an access permit is granted when the Minister is satisfied according to explicit criteria that the applicant has obtained the informed consent of the Indigenous owners and their benefit-sharing agreement is on mutually agreed terms. As the government is not party to the agreement or its benefits there can be no apprehension of bias.

Unauthorized commercialisation of resources

To date there have been few reported and verified examples of attempted unauthorized commercialization in Australia. The last significant example was the unsuccessful and unauthorized attempt to take samples of the "Smokebush' from Western Australia in the early 1990s. To date this issue does not appear to be a problem for Australia. Researchers appear to be honoring their contractual obligations. This perception, while at odds with popular perceptions, is shared by OECD researchers who concluded recently that, for at least the short term, unauthorized commercialization does not appear to be significant.[17]

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[16] The principle difference between the two being that the obligation to enter into a benefit-sharing agreement is not required for non-commercial research in favour of an obligation to share research outcomes, not pass the material onto third parties and to negotiate a benefit-sharing agreement should they later wish to commercialize their research.

[17] OECD Working Group on Economic Aspects of Biodiversity paper *Economic issues in Access and Benefit-sharing of Genetic Resources: a Framework for Analysis* (ENV/EPOC/GSP/BIO(2001)2/FINAL 04.11.2003

Topical examples of 'biopiracy' appear to largely the product of 'bad' patents eg the applications to patent turmeric, neem and varieties of stable traditional Mexican maize, or action taken in circumstances where no legal framework for genetic resources management existed. This raises the issues of the operation of patent systems rather than ABS issues. The Australian Law Reform Commission (ALRC) in its 2003 Inquiry into Gene Patenting and Human Health[18] examined the question of the need for improvements to the operation of the Australian patent system. In its report, *Genes and Ingenuity: Gene Patenting and Human Health* it has made extensive recommendations aimed at tightening the criteria for granting patents and for better decision making. The Australian government is considering these recommendations. It is noteworthy that many of the ALRC recommendations parallel those made by the United States' National Academies of Science to the US government in April 2004.[19] Any reduction in the number of such bad patents will clear some of the emotion from the international debate and reduce the cost burden on biodiversity managers needing to challenge patent decisions —often in foreign jurisdictions.

Monitoring and Enforcement

At present existing government contract management arrangements appear to be working well. The cost and administrative burden of such arrangements will, however, grow rapidly as levels of biodiscovery increase and new administrative arrangements are put in place to better reflect best practice as set out in the Bonn Guidelines. The Australian government has responded to this need. Over the next fours years it is providing guaranteed additional funding to enhance collaboration among jurisdictions in the implementation of the Nationally Consistent Approach. It is expected one immediate consequence will be the establishment of a body under the National Biotechnology Strategy to undertake that coordination.

Disclosure of Information: Patent Applications

In addition, there are two areas where considerable benefits lie in relation to both the cost and effectiveness of monitoring and enforcement. The first of these lies in the area of improved transparency. While public registers of permits enable managers, the scientific community, business, and venture capital to monitor what is occurring within a given jurisdiction, it does nothing to independently establish what discoveries are taking place globally - but based on the genetic resources of a given area.

The discovery process crystallises value at the point where Intellectual Property rights are taken out. Transparency lies at the heart of that process. The disclosure in patent applications of information about the source from which a discovery is derived and including information about the terms on which that source material was obtained, is of immediate benefit to all parties involved. For general researchers it indicates whether or not their own work risks intruding on another's, whether it is a source of new insights, and it tells where and possibly from whom, similar source material can be obtained. For resource regulators or managers it shows what is happening with their resources and whether contacts are being complied with. For the patent examiners, it may help them to decide whether an inventive step has been taken or resolve issues of prior art. For investors considering obtaining an interest in the IP, it enables them to undertake due diligence, addressing commercial and legal uncertainty and, to more accurately determine the market value of the IP. For industry capital providers, whether they are 'ethical funds' or simply concerned to protect shareholder value, they can determine issues of provenance and satisfy themselves that investing in companies owning the IP involves no risk to their own public reputation. Most importantly for the patent applicants, it allows them to obtain full measure of market reward for their compliance with their legal obligations surrounding their acquisition of the source material from which their inventions derive.

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[18] See URL: www.alrc.gov.au and follow the links.

[19] See URL: http;//4 nationalacademies.org/news.nsf/isbn/0309089107?open document

Disclosure of Information: Certificates of Origin

The second area of improved genetic resources management lies establishing a cost effective method of tracking downstream use of genetic resources both within a country and globally. The general introduction of registers of permits recording basic details of what is being collected and by who opens the way for the introduction of systems whereby each sample can be allocated given a unique identifier that then travels with each transfer through the value development chain. Information about samples as determined by the access approving body would be placed in a publicly searchable database. Each party acquiring the sample or indeed, merely acquiring an interest in the sample or something created from it, could then establish its source and provenance simply by reference to the identifier. If cost effective, such systems would increase certainty, promote the effectiveness of contractual 'reach through' provisions, and encourage investment and research and support compliance and monitoring of genetic resources. If developed into a common standard such identifiers would add value to the associated materials. It also adds a degree of transparency and confidence to each party otherwise engaged in otherwise private dealings that the subject matter of the transaction has a verifiable origin and traceable history.

Developing and Implementing ABS Regulations in the Pacific Rim Region: Issues and Challenges

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Introduction

In 1992, the Convention on Biological Diversity (CBD) provided a mandate for countries to develop national access and benefit-sharing (ABS) policies. In the last 12 years, however, countries have been burdened by the development process of these policies, encountering multiple obstacles and problems. To date only a limited number of countries have developed and implemented ABS policies. Pacific Rim countries, such as the Philippines, Costa Rica, Colombia, Ecuador, and Peru, have been pioneers in the development of such policies. These nations have had difficulties and successes trying to design and implement ABS regulations and they offer valuable lessons to other biodiversity-rich countries that are still planning to develop these regulations. Results of difficulty in implementation of these policies include the slowing of the flow of genetic resources between countries and reciprocal benefits.

These countries have also faced two contradictory issues in drafting national ABS policies to regulate access and exchange of genetic resources. First, restricting access is seen as a means to avoid domestic controversy and promote conservation by limiting overexploitation and by increasing the future value of genetic resources. On the other hand, providing access is necessary to generate a flow of benefits derived from biodiversity, including both commercial and scientific benefits. Given the importance of maintaining the flow of biological resources, benefit sharing, and conservation, a large scale and comparative analysis of different national experiences is warranted.

To this end, four scholars at the Davis and Berkeley campuses of the University of California launched a study of ABS policies and their implementation among 41 countries on the Pacific Rim. The study began in January 2002 and concluded in July 2004 and it involved the participation of over 60 ABS experts from the region (Carrizosa et al. 2004). The key objectives were to describe the main components of the access and benefit-sharing policies, the processes of drafting these policies and the experience of implementation. This paper presents a brief synthesis of the main results of the study and it focuses on some of the issues and challenges that have interfered with the development and implementation of ABS policies.

Main Results

The main results indicate that from the signing of the CBD until mid-2004, only nine Pacific Rim countries (22%) had developed some sort of national ABS regulation, 26 of them (63%) were working on their ABS frameworks, and 6 (15%) were not actively involved in a process working towards the development of ABS regulations. Countries have selected a wide variety of policy options that address ABS issues. For example, while countries such as Mexico decided to incorporate ABS provisions into existing environmental law, other countries such as Costa Rica decided to develop a specific Biodiversity Law that addresses not only ABS issues but also other objectives of the CBD. The following four main categories of policy options that address ABS goals were identified:

- Regional and national stand-alone ABS laws and policies (Andean Community of Nations, Malaysia, and the Philippines);
- Biodiversity and/or sustainable development laws, or environment acts that include biodiversity conservation and sustainable use provisions and ABS guidelines usually designed to implement the CBD as a whole (Costa Rica, Cook Islands, Honduras, Indonesia, and Nicaragua);
- Existing environmental, sustainable development or ecological laws that have been amended to include ABS provisions (Australia and Mexico); and
- ABS policies that may be developed further into more comprehensive ABS laws (El Salvador, Samoa, and Panama).

The analysis of selected ABS policies revealed several issues and challenges that have interfered with the development and implementation of these policies.

ABS Policy Issues and Challenges

More than any other natural resource policy, ABS policies have been the target of misconceptions, politics, and negative publicity. Biopiracy claims, poorly defined ownership rights over genetic resources, the patenting of life, the protection of traditional knowledge, and equity issues have thwarted access initiatives and have also contributed to the cancellation of bioprospecting projects in countries such as Mexico. Bioprospecting projects also remain the focus of fierce and intensive criticism by advocate groups that have great influence among indigenous organizations, government actors, and environmental groups worldwide.

The fact that most of these policies and projects will indulge or deprive specific stakeholders tends to mobilize them to shape policies in their interests. Taking into account the importance of this debate we examined the following eight key issues: ownership, scope, access procedure, prior informed consent (PIC), benefit-sharing and compensation mechanisms, intellectual property rights (IPRs) and the protection of traditional knowledge, in situ biodiversity conservation and sustainable use, and the monitoring and enforcement of selected national ABS policies. These are a few of the issues and challenges that can be identified from such analysis:

- The scope of most ABS policies covers nonhuman genetic, biological, and biochemical resources found in in situ and ex situ conditions. This broad scope has caused confusion among the users and providers of genetic resources about the type of activities that should be regulated by these policies. Since the main implication of Article 15(3) of the CBD is that *ex situ* genetic resources collected before the CBD entered into force are not covered by it, pre-CBD ex situ collections should not be covered by the scope of ABS policies. However, in practice, most ABS policies cover these collections.
- Access to pre or post-CBD ex situ collections has not been clearly defined by the ABS polices presented in this report. Ownership of these collections is still controversial.
- Monitoring bioprospecting activities is one of the most difficult, expensive, and resource consuming tasks. No Pacific Rim country has in place either a national or an international monitoring system. Once samples leave the country it is very difficult to follow their use and the exchange of information about them. Some countries might require bioprospectors to pay for monitoring and evaluation procedures or to purchase a compliance or ecological bond.
- PIC should be obtained from both national authorities and the providers of genetic resources and traditional knowledge. According to ABS policies, PIC from the government can be obtained through collecting permits or access agreements and PIC from the providers of

genetic resources or traditional knowledge (local communities) can be obtained through agreements or certificates that are usually the result of a consultation process. In any case, PIC procedures must be clearly outlined in a way that reduces time and transaction costs for bioprospectors and must also be simplified for noncommercial bioprospectors.

- It is interesting to note that Costa Rica's Biodiversity Law initially excluded plants, animals, and gene sequences from patenting. This exclusion, however, was repealed years later by an amendment to the national patent law. This is just one example of the conflicting views about the patenting of life that we found in many Pacific Rim countries.

ABS Policy Development Process: Complex Policymaking and Implementation Scenarios

How do policymakers deal with the complexity of ABS issues? Motivations are as complicated and multiple as are the policy objectives. Some policymakers complain about the complexity of the issues and users they face. The inability to face this complexity may be responsible for the failure to uphold appropriate standards of equity, respect for traditional knowledge, and biodiversity conservation. In any case, few things are more difficult for policymakers to do than to pursue the development of ABS objectives in complex policymaking and implementation scenarios.

The demands of interest groups, self-interest of specialized government and nongovernmental organizations, the complexity of the interactions within the system, and the possibility for unexpected and perverse side effects are ingredients certainly present in any policymaking and implementation processes carried out in countries such as Colombia, Australia, Malaysia and the Philippines. Furthermore, other countries have had to face social and economic crisis (Solomon Islands), severe shortages of trained personnel (Samoa, Cook Islands, Nicaragua), limited fiscal and technical capacity (Vietnam), fragile political relationships (Cook Islands), and weak institutions (Laos). In addition to these and other economic, political, or social conflicts, these and many other countries have had to address ABS policymaking and implementation processes in the context of different forms and levels of centralized and decentralized government structures that influence and determine opportunities for success or failure.

In most, if not all, of the countries examined, ABS policymaking and implementation was often regarded as synonymous with centralized top-down initiatives and decision-making was usually monopolized by national governmental organizations. This is the heritage of government regimes, where the source of all power is usually found in the nation's capital. Centralization of authority has been used in all societies as a way to improve both information flows and the ability to design and implement policies. A major and well-known problem of centralization is that technical expertise becomes increasingly scarce as one moves from the center to the periphery of a society and this is certainly the case in most of the countries examined in this report. This issue is compounded by the fact that ABS concepts are particularly complex and complexity implies the need for good information. The uneven quality of information among stakeholders influences the focus of attention.

Centralized expertise also fails to understand and respond to specific local conditions. In other words, the least powerful members of society may be exploited by local elites, they are literally invisible to centralized planners, and national elites always find ways of dominating policymaking. These least powerful members of society, particularly in developing countries, include unionized workers, bureaucracies, and farmer and indigenous communities. Another circumstance is that centralized agencies usually deal with local notables partly because the local elite is generally more articulate and better informed than the rest of the population.

Decentralization by itself, however, does not translate automatically into local people's participation in the policymaking and implementation process of ABS. Decentralization also requires incentives such as strong local capacity and effective participation channels. Our findings indicate that village cooperatives, labor unions, peasant organizations, and NGOs have become increasingly important channels for the activism of indigenous, peasant, and university-educated people. These participatory scenarios facilitate the articulation of a valid counterpoint to centralized governmental input that enriches the debate and contributes to more balanced ABS policies. Besides, common sense dictates that locally originated proposals can be aggregated and shaped to ensure that they are compatible with top-down policymaking approaches such as the CBD requirements.

In addition, in every participatory process, it is important to be aware of the subtleties of different stakeholders that are likely to determine the outcome of the development and implementation process of ABS policies. These include:

- Public authorities are not always responsive to public opinion. This is especially true when government organizations assume that they have sufficient technical capacity and expertise as illustrated by the development process of Decision 391, and
- On most ABS issues, many policymakers and other stakeholders do not have an opinion in the sense of having thought about the issue or having a consistent body of information about it. Instead most people are prepared to take a party line or position rather than invest time and effort analyzing a specific issue as exemplified by the development process of the Law of Biodiversity of Costa Rica.

ABS Policy Implementation

Implementation of ABS policies in the Pacific Rim region has been limited to a few cases. Between 1991 and mid-2004 most of the countries that have ABS policies invoked these frameworks to grant access to 22 bioprospecting projects. In the Philippines, only two out of 25 bioprospecting groups have been granted access to the country's biological genetic resources. Some of the problems experienced by Executive Order 247 were related to the scope of the law, the lengthy application procedure, prior informed consent issues, and biodiversity conservation issues. In 2001 the ABS policy of Samoa was invoked to negotiate a benefit-sharing agreement between the government of Samoa and the AIDS Research Alliance for the use of a compound derived from a local plant.

Implementation of Decision 391 in the Andean region has also been poor. In 1997 Colombia failed to negotiate a commercial access agreement under Decision 391 due to technical and political factors. Other access applications are on hold in Colombia until rules regarding the implementation of Decision 391 are clarified. Ecuador and Peru have also access applications on hold until national policies for Decision 391 are adopted. In Costa Rica, until now all access requests have been granted under the 1992 Wildlife Conservation Act and its 1997 regulation. Between 1991 and 2004, the National Biodiversity Institute and its partners in Costa Rica have implemented 15 bioprospecting projects. In Mexico, the Ecological Equilibrium Act granted access to three bioprospecting projects that were cancelled due to legal conflict and social protest. In the USA, the Federal Technology Transfer Act and National Park Service (NPS) policy was invoked to facilitate ABS goals for the Diversa/National Park Service project that is currently suspended until the NPS completes an environmental impact study.

The Costa Rican experience indicates that the chances of implementing effective national ABS policies are likely to increase in a decentralized context where the common denominator is strong local capacity and participatory mechanisms coupled with strong local government and nongovernment organizations. Furthermore, successful implementation of ABS policies will be facilitated when agreement and negotiation of projects take place between a minimum number of parties that share a common goal and with minimum intervention of bureaucracy and centralized government agencies. In contrast, and as demonstrated by the Colombian experience, an extensive and centralized bureaucratic process results in delays in the negotiation of projects that damage the morale and trust of implementers and recipients, thereby hampering successful implementation of ABS policy.

Conclusions

Only 22% of the countries analyzed in this study have developed some national ABS policy. This does not necessarily mean that countries have been inefficient, but rather cautious and inexperienced. Before the CBD came into force, most, if not all, of these countries had a permit system to regulate the extraction and management of biological resources. The transition from these permit systems to more comprehensive ABS frameworks has proven to be difficult as many countries struggle to find the economic means to develop such frameworks, the technical expertise or the much-needed consensus about new and controversial issues raised by the CBD. The political framework for access to genetic resources that any country will only be as good as the process through which it is developed. To actually work once established, the political framework must have the broad support of all relevant sectors of government and society, it must fit within the country's larger strategy for conserving and sustainably using biodiversity, and must be supported by decentralized institutional processes and capabilities sufficient to implement it. Building local capacity to improve policy development and implementation is a priority for all the countries reviewed in this study.

Finally, the 2002 Bonn Guidelines on ABS have provided guidance for the countries embarked on the development of ABS frameworks. However, governments and bioprospecting groups will continue facing controversial issues such as the patenting of life, access to traditional knowledge, and the perception that benefit-sharing agreements are not equitable. These are also some of the key issues that must be carefully addressed in order to facilitate both the development of national ABS policies and future efforts to negotiate an international regime on ABS.

Reference

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Briefing Note: National access laws (challenges), continuing monitoring and enforcement issues[1]

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Introduction

This briefing note focuses on five, often closely related, problem areas in the national implementation of access and benefit-sharing (ABS) regimes pursuant to Article 15 of the Convention on Biological Diversity (CBD):

- Misunderstanding of basic concepts;
- Lack of awareness of basic objectives and purposes;
- Disconnect between national needs and international framework;
- Lack of information creates protectionist reactions, and
- Dispersed capacity and lack of coordination.

The situations leading to each of these being considered as problem areas are examined in turn. The examples presented are not intended to be exhaustive but, rather, sufficient to illustrate each problem area. The potential effects of these problem areas on questions of implementation, in particular in terms of monitoring and enforcement, are considered as a conclusion to this note.

Misunderstanding of Basic Concepts

Definition of genetic resources

Misunderstanding of basic concepts in access to genetic resources begins at the most fundamental level: the definition of the term *genetic resources*. The majority of countries, and more particularly stakeholders and interest groups within those countries, have tended to assume clarity in this definition and have not considered issues such as natural/physical interpretations vs. political-legal interpretations or the relevance of national situations and interests. The key difficulty this creates is that ABS regimes have rarely clearly iterated what is, and what is not, regulated within their scope.

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[1] This briefing note is drawn from various experiences in facilitating national policy dialogue, providing technical assistance in legislative and regulatory development, negotiating collaborative and contract research agreements and surveying national situations and policy processes regarding access to genetic resources. These experiences are primarily from Africa but include some work in Asia and South America. The comments made and conclusions drawn are the author's observations during these experiences and do not reflect the official positions of either GRPI or SEAPRI.

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Interpretation: sovereignty and benefit sharing

Two further issues of interpretation appear to be common sources of problems in the national implementation of ABS regimes: national sovereignty and benefit-sharing.

A number of countries and actors have interpreted the CBD's recognition of national sovereignty as meaning state ownership. However, national sovereignty clearly refers to national rights to determine the ownership and control of genetic resources and not to any particular outcome of this determination. This question is critical to the structure of ABS regimes and may often be affected by existing legal frameworks, such as constitutional rights to property and land and tenure laws. Recognition of customary law and practice is also sometimes a feature of these existing frameworks.

On one level, the interpretation of benefit-sharing is an exact parallel to the question of ownership and control: who receives the benefits? On another level, it relates to the nature and form of benefits, with a tendency towards unrealistic emphasis on financial returns at the expense of historically more successful in-kind and reciprocal benefit-sharing strategies.

Intellectual property rights

The role and potential of intellectual property rights (IPRs) is frequently misunderstood with little distinction made between fundamental IPR principles and implementation policies. Many countries are also proposing the extension of the IPR system to new subject matter while simultaneously objecting to current asymmetries and the IPR implementation policies of other countries. Deeper analysis and exploration of prevention of misappropriation and freedom to operate based approaches combined with efforts to specifically limit some of the more extreme interpretations of IPR implementation might provide broader benefit sharing options and address some concerns regard abusive IPR practices.

Lack of Awareness of Basic objectives and Purposes

Reactive vs. proactive approaches

The clearest sign of a lack of awareness with regards the objectives and purposes of ABS is that most ABS regimes are being developed as direct reactions to the existence of the international framework and without any proactive effort to further identify national objectives. Most countries make little or no effort to identify national objectives, or approaches to internationally established objectives, and simply adopt international objectives without independent analysis. This reactive, rather than proactive, approach to developing national regimes means that governments are usually seeking to undertake policy development in an abstract context, without any reference to specific situations and interests, leading to fundamental flaws in the mechanisms adopted.

Failure to distinguish between sectors

One of the major drawbacks to reactive approaches is the unquestioning adoption of the relatively homogenised approach to ABS provided by the CBD framework. The weaknesses resulting from a failure to distinguish between sectors are best illustrated by the motivations for the development of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). However, the distinctions that have been made, such as between commercial and academic projects, have proven to be problematic. More sophisticated approaches, recognising the need for varying approaches to mechanisms such as access restrictions and benefit sharing requirements, are beginning to emerge in some countries but international discourse has, thus far, failed to recognise and adapt to these approaches. The majority of ABS regimes still tend to be developed through the generalisation of approaches to one sector to all other sectors.

Political and scientific contexts

The question of political context is largely one of capacities to assess one's desired objectives in terms of the objectives of other actors. Investing political capital in positions that other actors will never accept, or compromise with, is largely time wasted unless as a part of a wider negotiating strategy.

In terms of scientific context, countries have generally failed to take account of scientific standards and potential future developments in the formulation of ABS regimes.

Disconnect between National Needs and International Framework

Asymmetry between scale and nature of efforts at the national and international levels
A simple examination of the volumes of ABS-related activities at both the national and international level demonstrates a tremendous asymmetry of efforts in terms of time, resources and the application of available capacity. Even a number of activities that do work at the national level focus on translating international regimes down rather than bringing national interests and experiences forward for consideration at the international level.

Command and control, and often one-sized fits all, approach
As is suggested above, the international framework still tends to relate to national efforts in terms of command and control, usually involving one size fits all solutions. Rather than seeking to highlight how the international framework may further national objectives the emphasis is on how national systems must adapt to international rules.

Regulatory capture

The structures and funding available at the international level have tended to facilitate regulatory capture of national level ABS processes. Particular interest groups, usually promoting heavy regulatory approaches based on the experiences of limited sub-sectors, have tended to predominate, with only limited funding, and thus minimal access to policy processes, available to alternative approaches.

Lack of Information Creates Protectionist Reactions

Limited awareness of national policy (if there is one)

The limited amount of research and documented national level experience available suggests that the majority of stakeholders are generally unaware of any national policy processes and decisions, if these even exist. In such a situation, and in light of high profile reports of biopiracy and multi-million dollar genetic resource derived profits, stakeholders tend to assume the responsibility for filling the real or perceived policy vacuum.

Limited communication between sectoral actors

As much as key actors are unaware of national processes, they also tend to be unaware of each others interests and positions and therefore their unilateral approaches to ABS tend to reflect narrow perspectives and experiences.

Policy-making processes isolated from sectorial interests

The mirror of sectorial actors being isolated from national processes is that national level policy-making processes are equally isolated from details regarding the interests of these actors. Instead they tend to react to international pressures, as mentioned above, in combination with assumptions regarding national interests or information from well-placed narrow interests.

Individual reactions driven by perceived closed group advantage or desire to 'protect national heritage'

The relative isolation of actors in ABS processes tends to encourage individual protectionist reactions. This is partly the result of perceived comparative advantages among groups such as plant breeders or traditional health practitioners but belief in a personal role in 'protecting national heritage', usually from biopiracy, is also a common theme. Underlying all of these reactions appears to be some element of fear of the unknown: lack of knowledge of frameworks creates fear of abuse and of personal responsibility.

Dispersed Capacity and Lack of Coordination

Under-utilization of scattered capacity

The legal and policy capacity to develop and guide ABS regimes is generally scattered in developing countries, with very few reaching the critical mass necessary to address the issue comprehensively from their own resources. In the absence of resources to coordinate and develop this expertise, the tendency is towards excessive dependence on outside capacity with relatively generic approaches to ABS.

Means of keeping knowledge current a challenge

The scattered nature of capacity in ABS issues, and the large volume of information generated at the international level, means that there is frequently only a limited ability for individuals and groups to stay current with developing trends. This obviously limits the effectiveness of these individuals and groups but also probably hampers international debate, as national views and experiences are only sporadically presented.

Applied and theoretical knowledge often distinct

There is still a considerable divide among ABS practitioners between those working in applied and theoretical contexts. In terms of its effects this is similar to the issues raised above, i.e. it promotes a disconnect between pragmatic and conceptual approaches to regulation.

Lack of forward planning

Given that most ABS regimes tend to be developed as a response to external stimuli, whether this is the international framework, concerns over biopiracy or the availability of resources, they are generally short term in their outlook. Regimes are designed to address current concerns and are rarely effectively integrated into longer term conservation, scientific or development strategies.

Conclusion

At the national level, the primary problems in the development, monitoring and enforcement of ABS regimes are the facts that countries generally remain in a situation of applying systems and standards that do not reflect national situations and objectives. What a country is actually trying to achieve with its ABS regime is usually unclear and, in the absence of clearly defined localized objectives, there are no benchmarks against which to measure success or failure. In addition, expectations regarding the outcomes, in particular benefits, of ABS regimes are generally not based on any form of methodical assessments. As a result of these two problems, enforcement mechanisms are usually beyond the administrative, human and financial capacity of the states implementing them and virtually no thought is given to monitoring as there is little or no awareness of the nature of the activities that need to be monitored.

DISCUSSION PAPER
Access Laws: Challenges in Implementation, Monitoring and Enforcement

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It has been said time and time again, that the Convention on Biological Diversity (CBD) has created a new paradigm in regards to international and national access to genetic resources and benefit-sharing policies and laws.

This is, strictly speaking, true. Indeed, a considerable set of new regional and national policies and instruments (including institutional cods of conduct, treaties, non binding rules, policy orienting decisions, strategies, laws, regulations) have been crafted and put into force. Some of these include the FAO International Treaty, Decision 391 in the Andean Community, Executive Order 247 in the Philippines, the Bonn Guidelines, COP Decisions, institutional ABS policies in Kew Gardens, New York Botanic Gardens, Limbe Botanic Gardens, the ICBG projects, among other well known examples. These establish sometimes general, sometimes very detailed, procedures and institutional structures intended to regulate how and under what conditions biological materials can be accessed and utilized.

It is also evident that biotechnology related projects have increased in number worldwide and companies and institutions, especially (but not exclusively) in the North, are investing heavily in research and development (R&D) in this sector, in a search for new products in a wide range of areas and industries.

The key (still fully unanswered) question is whether, and how, this new paradigm shift has impacted R&D (and even conservation activities in general). Initial evidence would seem to suggest that although some institutions have taken important steps in adapting to this new situation, many consider these laws and policies (and some in particular) as excessively burdensome and a practical deterrence to continuing R&D activities.

Not that the CBD's ABS principles are intrinsically wrong, but simply that the manner in which some countries have taken steps to further develop them into laws and policies has been fueled by excessive economic expectations reflected in their laws and regulations. This argument may be more or less true. What does seem quite clear ten years after the CBD came into force is that: a) countries all over the world are having considerable problems in implementing and putting into practice their national laws and policies (for different and widely varied reasons) and thus, b) the benefit sharing principle (and underlying spirit of the CBD) has not been adequately met and realized. It could be useful to briefly speculate as to why this is so: a need for capacity building at the national level; incoherent laws and legislation; practical realities in the field; lack of total political commitment by some Governments, and a common and standardized (inadequate!) approach to ABS legislation.

Reasons may vary across the board and some may be more valid than others. The fact is that making the CBD work in practice —particularly in the area of ABS— has proved especially complicated in practice. It is quite interesting to notice how much the political and conceptual debate has "progressed", with ABS mentioned in almost every single international forum, ranging from WIPO and TRIPS Council to FAO, UNESCO, regional bodies, botanical congresses and so on. This is in contrast to the limited success stories available (or which have been documented) demonstrating how benefits derived from access to and use of genetic resources have been effectively shared.

Part of the problem has to do, perhaps, with the issue of actually documenting these stories and exposing the sometimes very discrete ways in which these benefits manifest themselves. Not every project and R & D effort will generate a blockbuster drug. This seems very clear. From teaching students collecting techniques to actually identifying an active compound there are literally dozens of steps and landmarks where in different ways benefits can be realized and eventually shared. Most people seem to be looking and scrutinizing for the royalty rate alone in this context, it could be argued that the manner in which benefits materialize and previous to that, incorporated into policies and laws, needs to be re evaluated.

On the other hand, an often overlooked and sidelined fact is that there is little hope in ensuring that the CBD's ABS principles (and all policies and regulations for that matter) are realized if there is no recognition that "countries of origin", by developing laws, will not be able to successfully implement these principles. Just the mere nature of genetic resources and emerging technologies and *ex situ* facilities and new areas of interest (deep sea beds and microorganisms) make the task of trying to regulate access to genetic resources on the provider side, particularly challenging if not impossible. The fact that 75 % of the world's *in situ* biodiversity is in a few megadiverse countries (including Canada and the US!) does not change this scenario, unless there is the thinking that border controls are an option.

The way in which one can overcome these problems is by proposing that ALL countries commit to ensuring the CBD's ABS principles are realized. Not only the "country of origin" but all countries in their providing/source and recipient capacities. This requires understanding that there may be common but differentiated measures needed to achieve this and that some countries may have a greater burden in doing so. Some interesting proposals have already been made and discussed in this regard, including adding requirements to patent applications and developing a certificates of origin system. The FAO IT Multilateral System is also an example of a mechanism in which parties share common but different responsibilities and burdens in relation to a closed set of resources.

In this regard, we would like to propose that the world does not necessarily need yet another international instrument (a protocol to the CBD as the reflection of an "international regime" which already exists!), unless it clearly addresses aspects which are not covered in existing instruments and policies. If for example, a negotiation focussed on obligations regarding the use of genetic resources *per se*, or centered its attention on biotechnologically derived products, or addressed some mechanism by which random international audits could be undertaken on certain projects (ABS related) to verify whether and how benefits are being shared, or even established a set of possible sanctions when contract or MTA provisions are not complied with, then we may be moving into interesting and potentially useful terrain.

We don't necessarily require more laws and regulations which state collaboration and cooperation as an objective. Five more years of discussions are not needed either (in our modest opinion). We need cost-effective measures (better laws) which efficiently promote collaborative approaches and attitudes among countries and institutions and, most importantly, focus on how best to make some of our existing tools and instruments more operational.

Without abdicating to sovereign rights nor putting aside the just, valid and certainly legitimate expectations and interests of countries rich in biodiversity, it is still possible to find alternatives and options by which genetic resources can generate benefits to them and their communities.

Section I

C: Access to Genetic Resources and Intellectual Property Rigths: What is Biopiracy?

What is Biopiracy?

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Context

The vast majority of countries formally recognize that cross-border exchange of genetic resources and traditional knowledge (TK) be carried out in compliance with the principles of the Convention on Biological Diversity. For a number of reasons, intellectual property rights, particularly patents but also plant variety protection, have become central to discussions on this matter. These reasons relate to the following:

- The conviction —widely held among developing countries and NGOs— that biodiversity and associated traditional knowledge have tremendous economic potential;
- The fact that patent claims in various countries may incorporate biological and genetic material including life forms within their scope;
- The belief, also shared by developing countries and NGOs, that this feature of the patent system enables corporations to steal, misappropriate or unfairly free-ride on genetic resources and associated traditional knowledge;
- The ability of modern intellectual property law to protection the innovations produced by industries based mainly in the developed world and its *in*ability to protect adequately those in which the developing countries are relatively well-endowed, and
- The perception that as a consequence of the above reasons, the unequal distributions and concentrations of patent ownership and the unequal share of benefits obtained from industrial use of biogenetic resources are closely related.

This paper deals with the third of the five phenomena, and seeks to shed some light on the meaning of the term "biopiracy" and to consider what should be done about it, bearing in mind that agreement on what is and isn't biopiracy, and how much of it there actually is, is still lacking.

Biopiracy as a Counter-Concept

"Biopiracy" has emerged as a term to describe the ways that corporations from the developed world claim ownership of, free ride on, or otherwise take unfair advantage of, the genetic resources and traditional knowledge and technologies of developing countries. While these and other corporations have been complaining about "intellectual piracy" perpetrated by people in developing countries, the latter nations counter that their biological, scientific and cultural assets are being "pirated" by these same businesses. Intellectual piracy is a political term, and as such is inaccurate and deliberately so. The assumption behind it is that the copying and selling of pharmaceuticals, music CDs and films anywhere in the world is intellectual piracy irrespective of whether the works in question had patent or copyright protection under the domestic laws. After all, if drugs cannot be patented in a certain country, copying them by local companies for the domestic market and/or overseas markets where the drugs in question are also not patented is hardly piracy in the legal sense of the word.

Similarly, biopiracy is an imprecise term, and there are good reasons to keep it so, at least in the international arena. But "strategic vagueness" is not a helpful approach for those working on legal solutions in such forms as national laws, regulations or international conventions.

Let us start by elucidating, as far as we can, the actual meaning of the word. To start with the obvious, "biopiracy" is a compound word consisting of "bio", which is short for "biological", and "piracy". According to the Concise Oxford Dictionary, "piracy" means the following:

1. the practice or an act of robbery of ships at sea
2. a similar practice or act in other forms, esp. hijacking
3. the infringement of copyright

Apart from the use of "piracy" for rhetorical effect, the word does not seem to be applicable to the kinds of act referred to as biopiracy. But let us now turn to the verb "to pirate". The two definitions given are

1. to appropriate or reproduce (the work or ideas etc. of another) without permission for one's own benefit
2. to plunder

These definitions seem to be more appropriate since inherent to the biopiracy rhetoric are the notions of unauthorized appropriation and theft. In essence, "biopirates" are those individuals and companies accused of one or both of the following acts: (i) the theft, misappropriation of, or unfair free-riding on, genetic resources and/or traditional knowledge through the patent system; and (ii) the unauthorized and uncompensated collection for commercial ends of genetic resources and/or traditional knowledge.

For biopiracy to mean anything at all, however, it cannot be considered merely as a matter of law but as also one of morality and of fairness. Accordingly, we need to acknowledge that where lines should be drawn between acts of biopiracy and legitimate practices is very hard to establish. The difficulty in drawing the line is compounded by the (deliberate) vagueness in the way the term is applied. To illustrate this point, it may be useful to explain and distinguish the terms 'theft', 'unfair free-riding' and 'misappropriation' by pointing out that they can encompass a broad continuum of activities from criminal acts causing serious harm, to legal but unfair activities, and even to legal, fair and socially-welfare enhancing uses of other people's property. For example, free-riding does not require there to be a victim, whether we speak of the person whose knowledge or goods have been freely ridden upon or of society as a whole. Indeed, some acts of free-riding may be of benefit to society and should therefore be allowed.[1] Consequently, there is likely to be considerable disagreement about how to distinguish between uses of somebody else's property that are legal, fair and social welfare enhancing, and other uses that are unfair or illegal and/or socially perverse in its effects. Behind much of the debate about biopiracy is disagreement on whether and to what extent such terms as theft, misappropriation and unfair free-riding should apply.

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[1] See MA Lemley, 'Property, Intellectual Property, and Free Riding'. Stanford Law and Economics Olin Working Paper No. 291, 2004.

To show how differently the term is applied, what follows is a list of actions that have been labelled as acts of biopiracy.

Traditional Knowledge Biopiracy

Collection and use:

- The unauthorized use of common TK
- The unauthorized use of TK only found among one indigenous group
- The unauthorized use of TK acquired by deception or failure to fully disclosure the commercial motive behind the acquisition
- The unauthorized use of TK acquired on the basis of a transaction deemed to be exploitative
- The unauthorized use of TK acquired on the basis of a conviction that all such transactions are inherently exploitative ("all bioprospecting is biopiracy")
- The commercial use of TK on the basis of a literature search

Patenting:

- The patent claims TK in the form in which it was acquired
- The patent covers a refinement of the TK
- Patent covers an invention based on TK *and* other modern/traditional knowledge

Genetic Resource Biopiracy

Collection and use:

- The unauthorized extraction and use of widespread resources
- The unauthorized extraction and use of resources that can be found in one location
- The unauthorized extraction and export of resources in breach of ABS regulations of the relevant country
- The unauthorized extraction and export of resources in countries lacking ABS regulations
- The authorized extraction of resources on the basis of a transaction deemed to be exploitative
- The authorized extraction of resources on the basis of a conviction that all such transactions are inherently exploitative

Patenting:

- The patent claims the resource itself
- The patent claims a purified version of the resource
- The patent covers a derivative of the resource and/or is based on more than one resource

What to do about Biopiracy?

The problem with the biopiracy rhetoric and the strategic vagueness behind it is that if you cannot agree on what it is, you cannot measure it. Neither can you agree on what should be done about it. One extreme view is that all bioprospecting is biopiracy. If so, the answer is to ban access outright. If biopiracy is merely an irritation, then such a ban need not be enforced too rigorously, since legal enforcement of higher-stakes areas of the law would have to take priority. If biopiracy causes demonstrable economic and/or cultural harm, the country should invest in enforcing the ban. On the other hand, if the problem is that provider countries or communities are unable to negotiate beneficial agreements, the answer may be to improve the provision of legal and technical assistance so they can. If the problem is that the patent system legitimizes or encourages misappropriation, then we may need to improve the standards of examination, ban patents on life forms and natural, or even modified, compounds, or incorporate a disclosure of origin requirement. In short, how you define biopiracy goes a long way towards determining what you should do about it.

Finally, I would like to suggest that it's possible to be too concerned about biopiracy. It's not at all clear that there is more bioprospecting now than there was in the past anyway. There's a lot of anecdote but very little data. Certainly, the pharmaceutical corporations generally consider themselves to be less dependent than ever on natural product research. For the Like-minded Megadiverse Countries, the main challenges are to enhance economic and social welfare through the more effective use of biodiversity at local and national levels, and how to ensure that traditional knowledge holders and the societies responsible for generating and maintaining TK get better protection from corporations and governments.

DISCUSSION PAPER

Access to Genetic Resources and Intellectual Property Rights: What Is Biopiracy?

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Biopiracy has been defined in a number of ways:

- Unauthorized use of biological resources;
- Unauthorized use of traditional knowledge;
- Unequal share of benefits to the provider, and
- Patenting without respect to patentable criteria of novelty, non-obviousness, utility.

Before determining a definition of biopiracy, it may be useful to set the scene by reviewing features related to the distribution and use of plant genetic resources for food and agriculture (PGRFA).

Important features of PGRFA are:

- No country has developed a successful agricultural system without recourse to non-indigenous plant genetic resources;
- All countries are highly inter-dependent for their supply of PGRFA;
- No single country is home to the full complement of crop species in their agriculture, and
- Developing countries will need ready access to PGRFA so they can develop their agricultures, just as industrially developed countries have had.

For example, Brazil is the country of origin and the ancestral home of cassava and peanut. Several other Central and South American countries, however, are also origin countries for cassava and peanut. Brazil, as an agricultural producing country, ranks in the following order among developing countries for the following crops:

- No 1 for soybean, maize, and citrus fruits;
- No 3 for cereals and apples;
- No 5 for cocoa beans, and
- No 6 for watermelons.

China, meanwhile, is the centre of origin for soybean, yet soybean varieties bred and used on farms in the United States are now being used in chines breeding programs to increase yields on farms in China.

Additional features of PGRFA that may be useful to consider are:

- PGRFA do not fit the pharmaceutical model.
- Global seed business = US$15 billion, pharmaceuticals US$235 billion (1990s data).
- Crop varieties have large genotype x location interactions and are often used only locally - a variety that is productive in one region of the USA may well be a failure in another region and fail to grow in other countries.
- Pharmaceuticals are far less dependent upon country location in regard to their efficacy.
- There may be many varietal substitutes or alternate choices, e.g. chemical pest control.
- There might be only 1-2 possible drugs.

What are the activities and who are the agents to bring forth more productive crop varieties?:

- Important activities - Actors
- Evolution of crop landraces - Farmers
- Conservation of PGRFA diversity on farms - Farmers
- Conservation of PGRFA diversity in genebanks - Publicly funded genebanks
- Breeding of more productive crop varieties - Public sector plant breeders / Private sector plant breeders

Who are the beneficiaries and who are the agents who create benefits?

The greatest value of PGRFA can only be realized in farmer's fields, in the agricultural production system. The major beneficiaries of a productive agriculture are consumers. The agents who allow these benefits to be created for consumers, constitute a chain linking PGRFA through the farm to the consumer. The agents can be categorized according to how they obtain financial resources:

- Private sector: Farmers and privately funded plant breeders
- Public sector: National and Internationally funded plant breeders and conservators, and Non-Governmental Organizations (may be privately or publicly funded, but provide public goods)

A proposed definition of Biopiracy:

Any activity that breaks the cycle of effort, investment, innovation, and creativity in developing improved crop varieties.

Eliminating biopiracy requires respect for contributions:

- CBD, national sovereignty
- FAO International Treaty; providing benefits into the multilateral system
- Traditional knowledge

- Respect for what is already publicly known
- Respect for developers of new varieties and innovations

Biopiracy leads to serious problems:

- Undermines investment in conserving diversity
- Undermines efforts into improving crop varieties
- Can lead to misrepresentation of varieties to farmers (same or similar varieties with different names)
- Reduces genetic diversity
- Reduces improved varieties for agriculture, thereby reducing farm productivity
- Unethical
- Unfair
- Undermines livelihoods, health, and the genetic resource base.

With the invention of agriculture some 8-10,000 years ago, humankind set a course that is dependent upon the cultivation and stewardship of domesticated animals and crop plants. Conscious human acts of genetic resource conservation, evaluation, crop improvement and good husbandry are ever more critical to maintain the plant genetic resource base upon which current and future generations must depend for food, health and environmental security. Biopiracy is a particularly important problem because PGRFA are biological, living resources and pirating can therefore not only lead to an undermining of efforts made by individuals or by organizations to conserve or to improve varieties, but also lead to the vulnerability and erosion or loss of the biological resources.

Respect and recognition should be provided to:

- **Farmers**, via the FAO Global Plan of Action, via the FAO International Treaty, via the CBD and as valued experts in crop husbandry and customers;
- **Nations**, via the CBD and support for the public sector (both national and International) from the private sector;
- **Public sector;**
- **NGOs,** and the
- **Industry-Private sector** to encourage investment in research and product development.

The private sector can encourage providers of germplasm or technologies via mutually agreed benefit sharing. The private sector should provide strong support for a public sector that can address needs not provided for by the private sector. The private sector should be open to honest criticism, and participate in constructive dialogue, debate, and learning.

Section II: Vision and Nature of an International Regime: Goals, Challenges, Gaps and the Role the CBD and Other Bodies

A. Vision And Nature of an International Regime

Vision and Nature of an International Regime on Access and Benefit-sharing (ABS)

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Introduction

Following decisions of the 2002 World Summit on Sustainable Development (WSSD), the 7th Conference of the Parties to the Convention on biological diversity has decided to start the elaboration and the negotiation of an International Regime on access to genetic resources and benefit-sharing (ABS-IR). The already existing Ad'hoc open-ended Working Group on ABS has been mandated to run the negotiation in collaboration with the Ad'hoc open-ended Intersessional Working Group on Article 8j and related provisions. This Working group on ABS should operate in accordance with the terms of reference contained in the annex of the decision.

In this short paper you will find some personal reflections on the future of the ABS-IR based on the outcome of the COP 7 meeting contained in decision VII/19 and focused on the following issues: objectives, scope, elements and nature of the IR as well as negotiation process.

Central Issues associated with the Negotiation of an International Regime (IR)

According to decision VII/19 operative paragraph 1, the aim of the IR shall be *to effectively implement the provisions in Article 15 and 8 j of the CBD and the three objectives of the CBD*. This is of course a very general and broad objective. It simply reflects the fact that the objective of the International regime was not discussed as such by COP 7. Therefore clarification of the objectives of the IR shall be one of the priorities of the Ad'hoc open-ended Working group.

The first question we might ask in this context is why do we need an international regime? Answering this question will require that each Party performs its own need/gap analysis of existing legal and other instrument at national, regional and international level. Based on the position expressed in previous CBD meetings we might however already assume that:

- Needs vary greatly from country to country (even among developing biodiversity rich countries), and

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[1] The views presented in this paper are solely those of the author and do not necessarily represent the views of the Swiss Agency for Environment, Forests and Landscape.

- Many important gaps have already been identified in the current ABS Regime (e.g. the Bonn guidelines) such as: (i) the lack of any obligation on Parties with users of generic resources under its jurisdiction to take measures to ensure compliance with PIC and MAT, and (ii) the lack of an effective dispute settlement mechanism.

One possible approach to clarify the objectives of the ABS-IR would be to look at the 12 objectives of the Bonn guidelines which are already more specific and practical oriented.

Another approach could be to categorize the 21 elements listed in decision VII/19 that shall be considered for inclusion in the IR. We did this exercise and ended up with the following outline (for information the letters in parenthesis refer to the elements listed in *part d* of the Terms of reference):

- Ensure fair and equitable sharing of the benefits (ii, iii, v, vi, vii, xii);
- Facilitate access for environmentally sound uses (iv, vii);
- Ensure compliance with PIC and MAT (ix, x, xi, xiii, xiv, xx) including Dispute settlement (xxi);
- Recognize and protect traditional knowledge (xv, xvi, xviii);
- Support capacity building (xvii, xix);
- Promote and encourage collaborative scientific research (i) including technology transfer (include basic research as well as R&D), and
- Address specifically the transboundary nature of some genetic resources and associated traditional knowledge (viii).

This outline could serve as a concrete starting point to discuss the objectives of the ABS-IR. When doing this, the following issues could be taken into consideration:

- How specific shall the objective of the IR be? How can we focus on practical oriented objectives?
- Shall the IR address all ABS related issues or focus on some elements such as enforcement of Prior Informed Consent or Mutually Agreed Terms including Benefit Sharing?
- How to address the concerns of indigenous and local communities? Can the objectives related to associated traditional knowledge be more specific?
- How to ensure an acceptable balance between rights and obligations as provider and user countries bearing in mind that most countries will be both user and provider?
- What shall be covered at multilateral level? What shall be addressed by national law? How to define the relationship between national and multilateral level?

Scope

According to decision VII/19, the scope of the IR is defined so far by the two following generic elements: genetic resources and traditional knowledge. Discussion shall take place to address the following issues related to scope:

- *Broad or limited scope?* Shall the IR address all genetic resources and related traditional knowledge like the CBD and the BG or shall it, like the FAO-IT, focus on specific groups of genetic resources (plants, animals, micro organisms etc.) or type of uses (commercial, taxonomic research etc.)

- *Comprehensive and simple*
- *Duplication with other forum and initiative*
- *Derivatives*
- *Multinational nature of some genetic resources*

Elements of the IR

In order to operationalize the IR, mechanisms and tools shall be developed. Examples of potential mechanisms and tools are listed below. Each of them shall be closely analysed in order to evaluate its pertinence and the best way and/or the most appropriate instrument to ensure its efficient and timely implementation.

- *Mechanisms to ensure compliance with PIC and MAT and to ensure fair and equitable sharing of benefits*
  - Disclosure of origin/source of genetic resources and traditional knowledge (user measure) in IPR applications
  - Certificate of origin/source/ legal provenance (provider measure)
  - Other systems such as standards and company certification
- *Dispute settlement mechanism*
- *Capacity building mechanism*
- *Mechanism to ensure the flow of information through the Clearing House Mechanism*
- *Collaborative scientific research and technology transfer*
- *Financial mechanisms*

Nature

The determination of the nature of the IR will, of course, depend on the clarification of the potential objective, scope and elements. Decision VII/19 is open on this issue since the IR could be composed of one or more legally binding and/or non-binding instruments.

The first step shall be to clarify and reach a common understanding on what we mean by both "an international regime" and "negotiate under the CBD". Are we going to develop a new protocol under the CBD as another international instrument on ABS or are we going to establish a framework or an umbrella instrument that might integrate already existing instruments or instruments under development? In other word will the ABS-IR be independent or integrated.

An integrated IR shall include already existing legally binding instruments such as the IT-FAO and voluntary instruments such as the Bonn guidelines pertinent for ABS. The development of additional instruments to fill the gaps could be foreseen both within and outside the CBD. The elaboration and implementation of a certificate system would be an example of a possible legally binding instrument that could be developed within the CBD. On the other hand, the proposed amendment to the Patent Cooperation Treaty (PCT) to include the disclosure of the source/origin of genetic resources and traditional knowledge in patent application would be an example of a new instrument developed outside of the CBD but integrated in the ABS-IR. The same could also apply to any development coming out of the WIPO Intergovernmental Committee on intellectual property and genetic resources, traditional knowledge and folklore.

The advantages and disadvantages of each approach should be discussed by the working group bearing in mind the particular needs of the countries and the foreseen duration of the negotiation process.

Process

Decision VII/19 required that the development of the IR shall be done in collaboration with the Working group on 8j and in cooperation with other international organizations such as UNEP, FAO, WTO, UPOV and WIPO. Even though a basis for collaboration and cooperation already exists, a new mechanism that offers more flexibility and efficiency shall be explored. This will pose new challenges in terms of process management especially if the option of an integrated IR is chosen.

Conclusions

For the first time in the history of the Convention on Biodiversity, decision VII/19, that kick-starts negotiation of the International regime on ABS, was imposed on the COP through commitments taken by Governments in other international bodies, the WSSD and the UN General Assembly. This might explain why COP 7 kept all options open and let the full responsibility of defining the objective, the structure and the legal nature of the regime fall on the Ad'hoc open-ended working group. In this regard the effective participation of indigenous and local communities as well as the close cooperation of other international bodies in the negotiation process will represent unique challenges. For CBD veterans, Kuala Lumpur looks like a reminder of Jakarta in 1995 where COP 2 decided to start the negotiation of a Protocol on Biosafety. It took 8 years for the Protocol to enter into force and it will probably take a few more years until this instrument is really operational. Can we wait so long for an international regime? Of course not, governments and all stakeholders shall continue to work towards implementation of the Bonn guidelines and the FAO-IT to gain sufficient practical experience. Based on this experience, governments shall negotiate simple and pragmatic measures to cover the most important gaps at international level. Only this might allow a rapid conclusion of the negotiation on the IR.

The International Regime from an Implementation Perspective: What Legislation Can (and Cannot) Do... and How this Affects the Vision and Nature of the Regime

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This paper presents the perspective of a researching lawyer/legislative specialist currently coordinating a team of lawyers on legislative and practical implementation of ABS. It focuses on two basic questions: (i) what is possible from a legal perspective? and (ii) what is needed to enable 'the possible'? The one thing that it does not do is give any opinion about policy controversies, such as whether a new instrument is needed, whether the regime should be "binding or non-binding', and how the negotiations should proceed.[2]

After twelve years, legislative draftsmen and agencies are still attempting to grapple with complex legal problems that hinder effective access and benefit-sharing (ABS) implementation. ABS is in some ways "unique"; it is a merger of some very new concepts of commercial law and science with the goals of conservation, sustainable use and equity. To address these unique qualities (regardless of which policy choices are eventually chosen), new legal concepts and tools are needed, as well as new uses of existing tools. Legal innovation, however, is not an easy process.

Consequently, an important goal in these negotiations could be for the policy makers to give ABS the one thing it lacks – a *"roadmap"* for the solution of legal impediments that currently inhibit implementation. These legal impediments must be solved before *any* ABS legal regime can function effectively. Hence, the "legal roadmap" process can begin immediately, in parallel with more controversial discussions, rather than waiting for them to be decided. At a minimum, such a roadmap could address two basic areas, the needs of *functional* ABS law and utilization of the tools of commercial and market-based (contractual) frameworks.

ABS and the Basic Elements of Effective Legislative Systems

Legislation is more than just 'translation' of policy into legal/legislative language. The legislative draftsman must create a system that addresses objectives, but also functions effectively. Functionality is needed in any legal framework – whether binding or non-binding, voluntary or mandatory. It depends on the lawmakers' ability to weave laws, regulations, contracts, permits, and institutions into a system satisfying five basic legal/systemic requirements:

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[1] This paper presents the views and 'expert input' of the author only. It does not, in any way, represent the views or policy of IUCN, its members, commissions, or secretariat.

[2] The author offers no opinion about the scope or results of 'negotiation of an international regime.' This paper assumes the goal of 'an *effective* regime' is shared by those who they feel a new instrument is needed (to 'create the regime') and those who propose review of existing instruments and processes (because they are not currently effective.)

- legal consistency (including human, political, property and intangible rights);
- clarity about what is forbidden, permitted, encouraged, and/or mandatory;
- mechanisms that protect and give legal certainty to all parties;
- practically implementable enforcement mechanisms, and
- consistency related laws, frameworks, systems and tools.

Functional Consistency

A legislative regime is "functionally consistent" where everyone who applies it can clearly know whether the regime applies, understand what it means, and apply it to factual situations. This is also called the "Rule of Law" where law and instruments are clear and rigorous, and where judges and administrators will apply legal standards rather than unfettered discretion.

In legal contracts and other instruments (including ABS), consistency means that the parties and others (including judges, in the case of dispute) know, with reasonable certainty, how all aspects of their arrangement will operate. Without it, the parties cannot determine whether the costs are reasonable or 'worth the effort.' Similarly, the system cannot function by waiting for a judicial determination on these matters for each negotiation. The draftsman must to create a system that is (i) unambiguous (clear and understood in the same way by all who review it), (ii) internally consistent, and/or (iii) governed by clear legal standards.

Regarding ABS, the Convention itself has hindered the creation of sufficient clarity, consistency and replicability. ABS implementation might be easier if the regime would provide:

- Certainty about which transactions and uses are covered by ABS, which transactions involve 'genetic resources' (requiring compliance with ABS) and which are 'biological resources' (which use conventional markets and instruments);[3]
- An effective legal means by which each source country can know of and protect its rights, after the genetic resources leave the country, and
- Accepted indicators that can be used to 'prove' that GR used in one country have come from a different country, and that the user has obtained a valid right to use them.

In the CBD negotiations, the Parties specifically opted not to negotiate clear provisions about what genetic resources are and how they are owned or transferred, leaving the clarification of these matters to national law.[4] By not clarifying this at the international level, however, the negotiators left countries un-guided. Most have not clarified the definitions in national legislation using the CBD definition, or adding other broadening phrases that do not add clarity.

One possible contribution of the international regime negotiations might be to clarify the meanings of key terms, including 'genetic resources' and the "use of genetic resources" and to address other uncertainties or deficiencies that have a legal/legislative effect.

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[3] The Author has prepared a separate paper on these definitional issues, entitled *"Genetic Resources" and "Utilisation of Genetic Resources – a Legislative View"*

[4] Glowka, L. et al, Guide to the Convention on Biological Diversity (1994)

Operative clarity

A legislative regime must clearly state which actions or conditions are forbidden, permitted, encouraged, or mandatory. In ABS laws, operative language generally focuses on two actions: the acquisition of genetic resources and the use of genetic resources. The CBD appears to assume that these will be 'permitted' either by general provisions allowing access and use of GR, or by laws stating that these activities will only be allowed with permission or ABS arrangement.

Consistent understanding is the first issue here. Users/providers/agencies must know objectively if a genetic or biological resource, or 'use of genetic resources' is involved. To enable enforcement, these facts (and the conditions of ABS arrangements and legislation) must be *objectively verifiable*; it must be possible to recognise and prove compliance/non-compliance from concrete facts and conditions that can be proven externally. Otherwise, in the case of violation, the system will not be enforceable among the parties, or in courts or administrative processes. The parties and officials must be able to prove compliance or non-compliance, or demonstrate their rights to a share of benefits or other remedy.

Once consistent understandings are codified, other key issues can be addressed, such as:

- *Procedures for obtaining ABS permissions*
  - public participation,
  - whether/how the government delegates its responsibilities for PIC, and
  - which person(s)/group(s) negotiate MAT and the limits on his/their authority.

Although not perfected, most countries' existing national law already contains procedural systems that can be models for PIC and MAT-related procedures in ABS. International experience and guidance on these matters, although often valuable, is only a supplement to the country's internal experience (the first and best guide to applying and implementing these requirements in its governmental/legal/cultural system.)

Remedies/controls for ABS compliance

There are fewer existing mechanisms as templates for ABS remedies in light of the ambiguity of certain key concepts. With objective ABS standards, it could be possible to use existing tools for ABS compliance.

Legal Assurance - Protecting those who Comply with the System

If it is to encourage governments, companies, and individuals to utilize the ABS system, the legal framework must meet two basic needs. One is consistency/predictability (see A.1, above).[5] The other is "legal assurance." The system must provide certain protection for the parties involved, including (i) governments, (ii) applicants, (iii) property owners or facilities that provide samples or allow them to be collected, (iv) user institutions, (v) middlemen, (vi) subsequent transferees, and

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[5] Research suggests that this factor is typically more important to users than a streamlined regulatory system.

(vii) other affected parties and beneficiaries (including those who acquire and use technological and commercial applications based on the GR). Each party invests time, money and other rights beginning with first negotiations. To encourage them to make this investment, their reasonable commercial expectations should be protected by law. This type of legal assurance is promoted where the legal framework clearly and objectively defines/protects the rights that provider and user acquire by complying with the system.

- *User Protection* appears to require:
    - a clear description of the rights granted in the ABS agreement, the limits of those rights and the responsibilities associated with them; and
    - assurance about how and when an ABS agreement becomes "final." Procedures for assuring finality can develop using existing laws as templates, once (i) is completed.

- *Provider Protection* appears to depend on:
    - ability to monitor the user, or to have certainty regarding post-access uses of the GR;
    - clear contractual statement, of the source's rights if the user violates; and
    - access to legal processes and incentive mechanisms where the resources are used.

Enforceability

For ABS, the enforceability question must initially be broken down into two categories – within the source country, and in other country(ies) in which the GR of the source country are used. In each category, countries have range of effective implementable enforcement solutions. Some of the challenges can be met through the regime negotiations, by the adoption (and trade-law acceptance) of (i) enforcement measures that deter both local and international parties from violating the law, (ii) mechanisms for source countries to obtain jurisdiction over the users and/or access to justice in user countries, and (iii) accepted evidentiary requirements (and enforcement capacity), enabling source country officials to make their cases successful in user country courts. Enforcement depends on *verifiable* evidence that meets the judicial standards of the country in which the enforcement action is taken (see A.2 above).

This raises two points. Firstly, enforcement questions must address two different kinds of 'actors': (i) Users under ABS arrangements who may be accused of violating those arrangements; and (ii) 'Bio-pirates' who take GR for commercial development without any ABS compliance. Secondly, many enforceability issues will only arise after the GR have left the source country. Current ABS monitoring seems to rely on reports from the user, raising two questions: How does the source country (and providers or communities) confirm reports? and, How can the source country determine that 'pirated' GR is yielding benefits to be shared?

Integration with other Relevant Laws and Processes

ABS implementation is one of a number of issues relating to genetic resources, property/sovereign rights, markets and other national laws, procedures, and social structures. The legislation must be consistent with broader national legislative frameworks or 'regimes.' In this regard, ABS presents interesting challenges, including its relationship with:

- laws on the marketing, purchase, sale, transport, and use of biological resources (from agricultural produce to wildlife to microorganisms);

- the biosafety framework, the protection of plant varieties/germplasm, food security, forests, transboundary waters and other source/habitat areas;
- legislative measures protecting communities embodying traditional lifestyles;
- the national system of laws relating to ownership of and transactions involving tangible and intangible property, and related sovereign rights and powers, and
- consumer protection and fairness in contractual/business negotiations and operations.

In practice, only where the ABS system has achieved an internal consistency and functionality can it be rationally integrated into a functionally rigorous national legal system.

ABS and Practical Components of Commercial Implementation

The need to create functionally consistent legislation is essential for any legal regime. This is particularly true where commercial or contract-based regimes may be applied and/or enforced by courts, and where elements such as consistency, clarity, and enforceability are essential. Where the legislation involves entities from other countries, these factors are more important. Beyond this, however, the development of a commercial framework such as ABS involves other factors (market forces and incentive systems) as key components of legislative success.

Integrating/Using Market Forces in ABS Regimes

There are several ways the international regime could improve the legislators' ability to utilize commercial tools (contracts, guarantees, and other trade instruments and controls) in ABS implementation. The CBD's ABS provisions create a new international market (in GR) and recognition of this new market could prepare the way for the appropriate use of these tools.

Presently, of course, the "ABS market" is virtually unregulated. Like traders in any other unregulated market, many parties to ABS arrangements cannot gain the necessary legal certainty to rely on 'standard contracts'. Instead, they develop specific (sometimes detailed and complicated) ABS agreements and processes to address the need for clear indicators about whether or how conventional mechanisms apply.

If the ABS negotiators specifically recognise ABS as a market regime, this may help signal the need for national and international application of legal concepts relating to the governance of markets in intangibles, controlled resources, and commercial transactions between parties of unequal 'power' in the transaction, including:

- Market transparency (mechanisms such as transaction registration and reporting) by which relevant market information (including value information) is provided to parties;
- Transactional disclosure (provision of relevant information fairly and truthfully);
- Market oversight;
- Transactional protection (ensuring "fair play" even in unequal situations), and
- Standards of commercial equity and fairness.

These kinds of controls already exist in most developed countries (to govern trade in stocks and securities, precious and controlled substances, futures, real estate, and other commodities), and most commercial transactions in fair and functional markets around the world are subject to some or all of them. Up to now they have not appeared in ABS implementation for a variety of reasons (discussed previously). Once basic legislative hurdles are resolved, however, the specific application of these protections to ABS would certainly be possible.

Strangely, although this may sound like an increase in complexity, these changes will almost certainly result in greater simplicity. A network of these principles and requirements would give comfort to parties to any given transaction (and their legal advisors) that their primary interests are being protected. They will be able to simplify contracts and contract-development processes. The result will be greater confidence by source countries and providers, streamlined processes, and increased legal certainty for users.

Finding Effective Incentives for ABS Compliance

However, 'picture perfect' legislation is not enough. For a legal framework to achieve its objectives, it must address and utilize practical motivations in a way that supports those objectives. Laws cannot rely on enforcement alone to motivate compliance. It is obvious that there are not enough enforcement officials to oversee every action of every person.

Consequently, the requirements of law are typically only one of several factors underlying private decision-making, especially where it relates to commercial matters. Commercial non-compliance, for example, usually occurs where (1) the actor concludes that, on the average, the cost and risk of being caught is less costly than the time, money, and other costs of complying, and (2) there is no other inherent motivation to comply with the law.

It can be difficult to find ways to enhance the motivation of users, source countries, and others to comply with the system. Unsupported generalizations and claims about incentives abound. However, when viewed in a practical perspective these claims often fall apart. There is an easy test of claimed "incentives":

- the incentive must provide a *benefit* to the person or entity whose behaviour it seeks to influence;
- this benefit must only be available if that person or entity engages in the *desired behaviour*; and
- the *perceived value of the benefit* must be greater than the cost of the desired behaviour. Unless all of these are true, the incentive will probably not motivate compliance among modern commercial operations.

Few of the 'incentives' that are offered as mechanisms for promoting ABS meet these tests:

- The public relations benefits of ABS compliance are limited by the fact that few members of the public have even heard of ABS, and virtually none understand it;
- International patent (PCT) and other legal rights systems currently do not appear to allow the conditioning of patent issuance on disclosure of origin in patent applications;
- The advantages of 'good relationships with source countries' although certainly important, may be less valued after the user takes the GR out of the source country, and
- There is no current indication that compliance with ABS will protect against future lawsuits or make other legal processes easier.

These are the primary 'benefits' suggested as motivations for ABS compliance by users. However, if ABS is operated under market/commercial law, it may also utilize market/commercial incentives. In essence, market incentives like most market activities, are the products of 'trade-offs'; the parties buy and sell based on what each item, right or activity is worth to them. Each party's situation is different, so each compares its internal valuation of whatever that they received against their internal value of whatever they gave

Currently, the market incentives in the ABS realm are not clear or compelling. This may, in part, be caused by the CBD's decision to separate the components of genetic resources. ABS processes, transactions and payments are completely severed from those of the products created.

For example, the ABS framework of issues is factually and closely linked to the Biosafety/GMO frameworks. The term 'genetic resources' appears to apply to both in the same way, and access to and use of genetic resources is directly (although not exclusively) connected to the goal of creating genetically modified organisms (GMOs). National and international legislation of these two issues is almost completely separated. In effect ABS has become a one-sided discussion of the interests of source countries and providers, while biosafety is a separate one-sided discussion focused on clarifying and simplifying the objective of GMO creators – the introduction of GMOs.

It is possible that by re-linking the various GR issues one may discern areas of negotiation and compromise between those promoting ABS transactions and those involved in GMO transactions thereby creating real commercial incentives on both sides of both issues.

The International Regime, as it Applies to Plant Genetic Resources for Food and Agriculture (PGRFA)

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The International Regime

The World Summit on Sustainable Development mandates countries *to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing....to effectively implement the [access and benefit sharing provisions] of the Convention [on Biological Diversity].* Those provisions spawned fundamental change in the realm of genetic resources.[1] Prior to the Convention on Biological Diversity (CBD), many regarded such resources as part of the common heritage of all mankind. And prior to the CBD there were discussions within the fora of the FAO and elsewhere about the global distribution, use, and benefit sharing from the use of plant genetic resources for food and agriculture. The CBD, however, confirmed that states have sovereign rights over their natural resources.

To a significant degree, the genetic resource provisions of the CBD were prompted by emerging applications of biotechnology in the pharmaceuticals industry. Those provisions are writ large, however, and encompass a broad range of application of genetic resources from drug development to industrial manufacturing to consumer products to agriculture. In each such context, CBD mandates have been superimposed upon conventional practices under which applications and uses of genetic resources have evolved. These practices vary among applications, as do their history and global breadth.

This variation has very significant implications for the nature and content of any "International Regime". Nowhere is this more evident than in the realm of plant genetic resources for food and agriculture (PGFRA), where deliberate use and modification of genetic resources has been under way for thousands of years; and where an elaborate array of institutions and protocols have evolved to encourage and facilitate both the development of such uses and the global sharing of benefits derived from these developments.

The following paper uses the specific example of PGFRA to illustrate both unique aspects of these applications of genetic resources, and a range of considerations more generally applicable to any "international regime".

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[1] Under the Convention, "genetic resources" has a broad interpretation that includes "any material of plant, animal, microbial or other origin containing functional units of heredity" that is of "actual or potential value" (Article 2).

The Critical Importance of PGRFA and the Goals of an International Regime

Field trials growing old and new (1930s to the present) US Pioneer brand maize hybrids show that newer hybrids outperform older hybrids no matter the weather. In a drought year, yields using 1990s hybrids are 10 tonnes per hectare compared to 5 tonnes per hectare using 1930s hybrids. In ideal growing conditions, 1990s hybrids yield around 13 tonnes per hectare; nearly double the yield of 1930's hybrids. Improved yields are due to plant breeders assembling new combinations of genetic diversity from among a broader pool of genetic diversity. The continued development of new varieties that are improved by virtue of their genetic make-up is essential:

- to meet human needs for food, health and economic security;
- to reduce pressures on the environment from ploughing wild and fragile lands;
- to allow adaptation to changing weather (drought, salinity) and ever evolving pests and diseases, and
- to help reduce chemical inputs and thus contribute to a cleaner environment.

It is therefore essential to further enhance the processes of accessing and improving plant genetic resources for food and agriculture. Diversity that cannot be accessed represents potential lost opportunities for farmers and for consumers. Access to plant genetic resources goes beyond legalities and includes biological parameters. Genetic resource diversity may be inaccessible because its potential is unknown, or it is too risky and time-consuming to incorporate into an adapted variety, or because there are legal uncertainties relating to access and benefit sharing. Plant genetic resources for food and agriculture only become useful when they are grown on farms and contribute to agricultural productivity. The goals of an International Regime must therefore be to facilitate access and benefit sharing from the use of genetic resources. Ideally a regime would address both the legal and biological issues that affect access, use and benefits.

Access and Benefit-sharing for PGFRA: Features and Limitations Imposed by History, Biology and Laws.

Who are the beneficiaries? Benefit-sharing is usually discussed in the context of benefits that flow back to providers of genetic resources. However, benefit-sharing in respect of PGRFA should be understood in a much larger context; one that is global and multi-generational. By far the greatest number of beneficiaries are downstream of where PGRFA are accessed, further developed and then used in agriculture. Each of us as consumers of food is a beneficiary. Future generations will be beneficiaries provided mechanisms are established that encourage sustainable development, stewardship and use of genetic resources that will continue to improve agricultural productivity whilst protecting the environment. These mechanisms must encourage the more effective use of PGRFA on farms. It is in the more effective use of PGRFA that benefit-sharing in its more usually understood and narrower context comes into focus. It is important to identify the activities and the actors who contribute to the use of PGRFA, and it is also critical to consider the nature of PGRFA in respect of their global distribution and use.

What are the activities? Activities that are essential to further improve varieties are: conservation of PGRFA, evaluation of exotic germplasm, pre-breeding or germplasm enhancement programs, breeding of improved varieties, production of crops, and continued scientific research. Farmers have traditionally played the roles of conservator, varietal improver, and producer of food. Farmers who cultivate landraces today continue to play these three roles. In most of the industrialized world, and increasingly in the rest of the world, however, specialist roles have emerged. In these specialist roles conservators are usually funded publicly; pre-breeding or germplasm enhancement is largely funded by public funds, plant breeders can be funded either by public funds, which may be national or international programs or through private, commercial funding, and farmers rely upon sales of their harvested crop for income. Conservators, pre-breeders, breeders and farmers can each be viewed as engines of activity. Each is essential to create a continuum starting with the conservation of PGRFA, access to PGRFA through the further improvement of crop varieties, to the growing of crops on farms and their harvests so that benefits ultimately accrue to consumers. " Without sufficient diversity, we play a waiting game, waiting for the pests and diseases to get the upper hand and assign a crop to extinction and the history books" (Cary Fowler).

Features of PGFRA that must be addressed by an International Regime

Diversity and inter-relationships: The diversity of actors, multi-national dependencies for genetic resources, and the long-term public benefits from conserving a broad base of genetic resources, mean that a workable international regime for PGRFA must accommodate and encourage the need for both public and private investments. Shortfalls of capacity in one country have negative spillovers for other countries and therefore need to be redressed. Needs of farmers for improved varieties that are insufficiently provided for should be addressed. Multinational dependencies mean that shortfalls or a lack of capacity in one country undermine opportunities for all. And recognition needs to be provided for farmers' contributions to the development of crop diversity.

The nature of PGRFA: Varieties grown today in farmer's fields have pedigrees that cross countries and which often span continents. Pedigrees of varieties bred in plant breeding programs can usually be traced back to founder varieties used when those programs commenced during the 1930's-1960's. Farmer landraces trace back 8-10,000 years to sites of original domestication from wild relatives. For example, maize was originally domesticated in Oaxaca, Mexico. Varieties known as landraces were then developed by farmers as seeds were carried north and south and selection occurred in different environments. Maize landraces were present in the southwest of the territory now known as the US by at least 3,500 BC and they were also grown by indigenous people in the region that is now known as New England by at least 1000 AD. By 1600 maize had spread across Europe, Asia and Africa.

Examination of pedigree backgrounds of maize hybrids developed by Pioneer Hi-Bred that were widely used on farms in the United States, France and Mexico during the 1990s shows that pedigrees track to several founder varieties or populations. Some pedigree backgrounds are common in hybrids grown in different regions of the world (e.g. US landraces Leaming and Reid Yellow Dent, developed 1840-1860). In contrast, other germplasm backgrounds are restricted in the country of deployment. For example, Mexican landraces Tuxpeno and Zapalote Chico are present in Pioneer hybrids grown in Mexico, but not in hybrids grown in the US or France. In contrast, several examples of pedigrees that cross countries and continents are also evident. For example, FSOP was developed in the US but is used in hybrids grown in Mexico; Argentinean Maiz Amargo had its origins in Argentina and now appears in pedigrees of hybrids grown in both the US and in France; P54 a hybrid once grown in Cuba appears in the pedigrees of hybrids grown in Mexico.

PGRFA do not fit the pharmaceutical model: Access and benefit-sharing regimes are often considered using a pharmaceutical type model. In this model, a unique genetic resource is envisioned that has great monetary worth because access can be controlled and the product it is used in is in high demand and can command a high price due to a lack of substitutes. However, the model for the vast majority of plant genetic resources used for food and agriculture presents a different set of realties.

The global spread of varieties over millennia means that it will be unusual to find a unique genetic resource in one location. And alternate choices are usually available, for example chemical control can be used in place of a gene for pest or disease resistance. Most usually, then, specific PGRFA are neither rare, nor can they command a high price. In addition, local efforts are usually needed to identify useful PGRFA and to develop new crop varieties. In contrast, many drugs can be effective regardless of the country in which they are developed or where they are used. The historical transfer of crop varieties around the globe also means that it is usually impossible to track a variety grown today back in its pedigree to its origin thousands of years ago.

The main challenge: Promoting more access and use of PGRFA: It is the historic and continued transfer and improvement of plant genetic resources, a process that has evolved over millennia, which provides the basis for developing more productive varieties. Access to genetic resources is necessary to allow development of improved varieties that can be used on farms. Yet PGRFA for the most part do not fit a bilateral pharmaceutical type model. The solution has been to develop an internationally agreed multilateral framework where access to PGRFA is assured: assured access is itself the major benefit that removes the need for countries to undertake the laborious task of developing potentially hundreds or thousands of bilateral agreements. Access and benefit-sharing for PGRFA has therefore trodden two complimentary paths. One is a multilateral approach for specifically listed crops that was directed to the Food and Agriculture Organisation (FAO) of the United Nations under the auspices of the Convention on Biological Diversity (CBD). The second is a bilateral approach that is being developed by the CBD itself. The bilateral approach deals with access to varieties (listed and unlisted) that are currently extant in farmer's fields, that are not listed species, or any species for which use is non-agricultural.

The Multilateral Approach: The International Treaty

The Multilateral System (MS) was adopted in November 2001 by over 100 nations. It came into force as the FAO International Treaty on June 29th, 2004.

The objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. Through the Treaty, countries agree to establish an efficient, effective and transparent Multilateral System (MS) to facilitate access to PGRFA, and to share the benefits in a fair and equitable way. The MS applies to over 64 major crops and forages. The major gene bank collections currently held under the auspices of the FAO in CGIAR genebanks are expected to be part of the MS. The Governing Body of the Treaty, composed of countries that ratify the Treaty, will set out detailed conditions for access and benefit-sharing in an Material Transfer Agreement (MTA). This standardized MTA may well prove to be an important model for other genetic resource areas under the International Regime.

Conditions for access: PGRFA may be obtained from the MS for utilization and conservation in research, breeding and training. When a commercial product is developed using these resources, the Treaty provides for payment of an equitable share of the resulting monetary benefits, if this product is restricted from use by others for further research and breeding. If others may freely use the newly developed variety in their breeding programs, then payment into the MS is voluntary. Privately funded plant breeding organizations rely upon effective intellectual property (IP) on the varieties they create to underwrite continued investments in research and product development. The international treaty therefore respects and accommodates the need for organizations to obtain IP. Principle donors to the multilateral system will be governments.

Benefit Sharing: The Treaty provides for sharing of the benefits of using PGRFA through information exchange, access to and the transfer of technology, and capacity building. It also forsees a funding strategy for activities that benefit small farmers in developing countries. Benefits of the International Treaty flow to:

- farmers and their communities by recognizing the contributions of farmers and communities to the conservation and development of PGRFA and giving governments the responsibility for implementing those rights;

- consumers, because of a greater variety of foods, agricultural products, and increased food security;
- the scientific community, through access to plant genetic resources crucial for research and plant breeding;
- international agricultural centres, whose collections the Treaty puts on a safe and long-term legal footing;
- both public and private sectors, which are assured access to a wide range of genetic diversity for agricultural development, and
- the environment, and future generations, because the Treaty will help conserve genetic diversity to face unpredictable environmental changes, and future human needs.

The bilateral approach: The CBD *per se*

Bilteral agreements providing access to and use of plant genetic resources under the guidelines of the CBD (Prior informed consent and benefit sharing) are still important for PGRFA because they include varieties that are grown *in situ*, wild species and non food or feed uses. No market can exist without both the supply and demand for PGRFA, and it is important to reiterate that access to PGRFA is dependent upon biological and legal factors. PGRFA that could be useful in agriculture will languish and be under-utilized, failing to produce additional benefits to consumers or to would be germplasm providers, unless there are programs in place to explore the utility of those genetic resources. Opportunities to identify PGRFA that may be useful in another country are very dependent upon in-country pre-breeding and breeding programs. The multi-national pedigrees of Pioneer maize hybrids, for example, demonstrate that a breeding program in Iowa is in effect also a pre-breeding program for France. Countries cannot expect to experience a demand from breeders in other countries for use of their *in situ* germplasm unless there are in country breeding programs to uncover potentially useful germplasm. Consequently, the goals of the CBD to encourage sustainable use of genetic resources cannot be met if only the legalities of ABS are worked out. The biological challenges of identifying and encouraging the use of exotic genetic resources must also be resolved.

A contractual approach: A contractual model could be envisioned with full up-front disclosure and transparency. Benefit sharing terms would be agreed between parties so that accessors would know ahead of investing in research and product development their commercial liabilities. Sanctions for non-compliance would need to be in place to provide an essential basis of trust between parties. Policing via patents has often been mentioned. It is important to note, however, that placing additional demands on patents not only serves to weaken investors willingness to invest in research, it is also an inefficient option for the genetic resource provider. Most developments of PGRFA do not end up in the form of a patent, and even when they do it is not usually the patent that creates the monetary flow; the monetary flow commences with the sale of the product that contains the genetic resource. Other means to track genetic resource use or to validate compliance might include certificates of origin or source and codes of conduct. Annual reports documenting use of the genetic resources might be envisioned, possibly with their party audits. Civil penalties for companies that bio-prospect without an ABS agreement could be appropriate including suspension of rights in the country, withdrawal of visas and/or monetary penalties. International arbitration tribunals may be needed for dispute resolution. However, it will be important to keep costs low. Developed countries should provide capacity building to assist developing countries to effectively negotiate with companies.

The CBD obligates members to facilitate access to genetic resources. Referencing owners of genetic resources or providing a registry of agreements could be useful. County focal points that can clearly identify parties that have authority to negotiate access and benefit sharing terms are critical needs. And it is essential to emphasise once again that plant breeding programs are required to identify potentially useful germplasm. There are few prospects of requests for access to exotic germplasm without the evaluation of those resources that can occur within an in country breeding program.

Conclusions

Continued access to and use of PGRFA is critical for human health, economies and the environment. The greatest value of PGRFA is realized in farmers' fields, in the agricultural production system. It is important to encourage yet more effective access to and use of PGRFA. Both public and private sector activities are required. Effective IP is an essential prerequisite to encourage innovation and risk taking in the use of PGRFA by commercial breeders. The FAO-IT and CBD together provide two complementary paths forward to facilitate access, benefit creation, and the sharing of benefits. Both accommodate needs of commercial breeders to obtain IP on derived varieties. It is important that the needs of both the providers and the users of genetic resources are met. Otherwise, there will be breaks in the continuum linking PGRFA that flow ultimately through farmers to consumers. Breaks in the linkage between PGRFA and consumers mean that agricultural productivity declines and additional pressures are then put on current and future generations to maintain food, health and environmental security.

Plant breeders have grown accustomed to licensing important traits and technologies. Building trust is an important component to effective access and benefit sharing. Experiences of commercial companies, who are often both providers and accessors of germplasm or technologies in license type agreements, may be useful to help countries gain experience and confidence in developing bilateral agreements. It is also crucial to focus resources to meet the biological constraints in identifying and using exotic genetic resources. An international regime with legal certitude will remain non-functional unless additional resources are applied in field breeding programs to identify potentially useful exotic germplasm.

Vision and Nature of an International Regime: Minimum Requirements and Options from a Practical Developing Country Perspective[1]

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Substantive Issues

A. Minimum requirements

Core objectives of an international regime

The core operative objectives and associated mechanisms of any international regime should be clearly iterated as soon as possible. Recognising there is considerable difference of opinion regarding some aspects of access to genetic resources and that the process of international negotiations inevitably introduces some element of ambiguity into final text, these operative objectives and associated mechanisms should be relatively few and approached in the simplest manner possible. Anything overly complex will stretch the capacities and resources of developing countries and risk the perpetuation of fears regarding asymmetries in the utility of the system to different regions, sub-regions and interest groups.

User country and enforcement measures

User measures, and the related questions of enforcement and compliance, are the central issue that must be addressed by any international regime. The key weakness of even the best formulated and implemented access and benefit-sharing (ABS) policy or regulatory framework is that users of genetic resources are frequently not based in the country of immediate origin of those resources. This is primarily an issue of countries agreeing to respect each others legal and policy principles and measures regarding access and benefit sharing. However, a clear distinction should be made between the activity of 'access' and downstream principles regarding 'use'. Countries will not necessarily need to recognize each others policies and laws regarding patentability and similar matters in a general sense but, rather, will only need to agree to recognize the terms and conditions attaching to 'access', which may or may not include case-specific restrictions on patentability etc.

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[1] This briefing note is drawn from various experiences in facilitating national policy dialogue, providing technical assistance in legislative and regulatory development, negotiating collaborative and contract research agreements and surveying national situations and policy processes regarding access to genetic resources. These experiences are primarily from Africa but include some work in Asia and South America. The comments made and conclusions drawn are the author's observations during these experiences and do not reflect the official positions of either GRPI or SEAPRI.

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In this context any international regime should make user measures a universal requirement on the basis that access is not always a question of developed country actors accessing genetic resources from developing countries.

Accompanying any provisions on user measures is the need for an approach to enforcement. The civil legal systems of developed countries are still largely inaccessible to developing country actors and the option of establishing criminal penalties for irregular activity, now a major feature of intellectual property rights systems has, thus far, only been discussed in a limited manner in developing countries. The absence of an effective means to enforce or protect one's rights means that, in practice, one has no rights.

Monitoring mechanism

Some form of limited monitoring mechanism, as is currently being proposed by some experts in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture, should be considered. This mechanism would not need to have a particularly heavy mandate but could concentrate on tracking trends and screening and forwarding complaints for the consideration of the international regime's governing body. If this mechanism identified widespread patterns of abuse the governing body should have the authority to consider any further measures that might be necessary to limit such behaviour.

Minimum standards and harmonization

There should be no general approach to minimum standards or harmonization and any efforts in this regard should be strictly limited to the core objectives of an international regime. The differences of opinion on key issues and the relative asymmetries in negotiating power regarding these issues preclude the development of any comprehensive 'global ABS' regime. Relatively recent experiences in the context of TRIPs and the proposed Substantive Patent Law Treaty have highlighted these facts. In addition, information on the ground increasingly suggests that a wide degree of flexibility in the nature and structure of access regimes between, and even within, countries is a prerequisite for the development of effective systems.

An effective regime addressing user measures would allow countries to establish and experiment with their own standards and approaches safe in the knowledge that these would be respected in other countries.

B. Additional options

Categorization

Work on the identification and description of the various uses of genetic resources might assist countries in recognizing the radically different dynamics that apply in some of these uses. Such a recognition would further the development of national ABS systems to cater to the needs of different users while the use of any categorization system in formal approval processes might allow for some tracking of trends and interests in the field. Such a system might be modelled on existing examples such as the International Patent Classification.

Supporting Components

Information clearing and monitoring

Some form of information clearing system covering regulatory and policy approaches, experiences and ongoing developments could be useful, particularly if it considered monitoring developments in scientific and commercial practice regarding access to genetic resources. Despite constructive efforts by the CBD Secretariat (and to some degree WIPO), the primary sources of practical information for those regulating, or negotiating, access to genetic resources are informal international networks of individuals who, for one reason or another, are aware of each others' activities and share some measure of trust. While these networks can be effective for those with access to them, they perpetuate an exclusive model of expertise in ABS and isolate many individuals and organizations in need of assistance and advice. It should be recognized that this need for assistance and advice exists in both developed and developing countries and in both the public and private sectors. Many actors simply do not know how they should approach ABS issues even though their intentions are good.

Capacity building

National level capacity building, particularly in policy analysis and implementation, remains a critical need in the field of ABS. Most countries do not even have the capacity to assess whether ABS capacity building would be a worthwhile exercise, in terms of opportunity cost, for them or not. A number of ABS regimes, and processes for developing such regimes, have proven to be dysfunctional because the actors involved simply did not understand enough about what they were trying to achieve and why.

In the event that countries determine that formal ABS systems with more than minimal access procedures are appropriate for their situations, capacity building will also be required to ensure that there is at least some ability to implement and oversee such a system and to forward experiences to the international level in a coherent manner.

Conclusion

The main challenges facing the development of an international regime are twofold. One is the often polarized views of some actors and stakeholders regarding ABS related issues and the risk that these actors and stakeholders will refuse to support any international regime that does not accommodate their view. This is the primary reason why any regime should focus on clear issues that have achieved widespread, if not always universal, acceptance. The second challenge is that national level capacities in many aspects of ABS are still extremely low leading to decisions often being made on the basis of faulty assumptions and much international, and even national, discourse being characterized by mistrust and combative positions. Greater attention to national level capacity, combined with the development of effective user measures, will reassure developing countries that they understand ABS issues sufficiently to be able to comfortably engage in collaborations with developed country actors.

DISCUSSION PAPER
International Regime on Access and Benefit-Sharing (ABS): Exploring New Options for Achieving CBD-Related ABS Objectives

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Overall Vision

The need for continuing exchange of information between the CBD and WIPO and the need for mutual supportiveness of these organizations in pursuance of matters of common interest in relation to access and benefit-sharing (ABS) (concerning disclosure of the origin of genetic resources and related traditional knowledge in applications for intellectual property rights, including those raised by a proposed certificate of origin, source, and its legal providence) are emphasized. Kenya wholeheartedly approves of the cooperation between the CBD and WIPO in addressing the issue regarding the interrelation of access to genetic resources and disclosure requirements in IP documents.

Kenya has no specific regulatory regime on ABS in place. Although a potential regulatory structure has been put in place, it is yet to be developed into a substantive regime. There is a range of statutory, regulatory and policy provisions regulating access to genetic resources. The primary document in this case is the National Biodiversity Strategy Action Plan that stipulates National Policy on Biodiversity and Trade in Genetic Resource based products and processes.

Section 4.11 of the strategy states that Kenya will develop and implement policies and legislation to articulate and regulate the rights of access to, and benefit sharing of National Genetic Resources. It will strengthen the capacity of Kenyans to carry out bioprospecting activities.

Action 19 provides that Kenya will facilitate access to genetic resources and transfer of technology, and that Kenya Wild life Services (KWS), National Museums of Kenya (NMK), the National Council for Science and Technology (NCST), and Universities are the lead agencies. Action 21.4 provides that it will explore options and modalities for access and benefit sharing in the National Context and the lead agencies are, NMK, NCST, Universities, national research institutions and NGOs.

National Access Laws, Challenges, Monitoring And Enforcement Issues

Kenya has had a series of laws and regulations dealing with access for many years. Prior to the CBD, they were embedded within rules on research, collecting and export. They remain in different spheres, though CBD-related developments have begun to plug some holes and bring together the national actors. Issues of benefit sharing are only now being examined with some rigor.

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[1] This paper reflects the view of the author and is not an official statement of the Kenyan Government.

Environment Management and Co-Ordination Act (EMCA-1999)

EMCA-1999 is Kenya's framework legislation, co-coordinating all environmental management activities in the country and constitutes one primary implementing legislation for the Convention on Biological Diversity (CBD). Section 53 of the Act mandates the National Environment Management Authority (NEMA) to issue guidelines and prescribe measures for sustainable management and utilization of genetic resources of Kenya for the benefit of the people of Kenya.

The guidelines specify appropriate arrangements for access to genetic resources of Kenya including the issue of licenses and fees to be paid for access, and measures for regulating the import and export of germplasm.

The sharing of benefits derived from Kenya's genetic resources, bio-safety measures necessary to regulate biotechnology, measures necessary to regulate the development, access to, and transfer of biotechnology as stipulated, in the context of Articles 15 and 16 of the CBD, are also considered.

Requirements and Process for Foreign Parties Accessing Genetic Material

To undertake research of any kind within Kenya, the Office of the President (OP) and the National Council for Science and Technology (NCST) are key agencies in granting permits for research programs, including that to access genetic resources. The OP grants, based upon advice from the NCST, act as authorization of for all research permits in Kenya, whether for Kenyans or foreigners. The granting of research permits is necessary but does not constitute fully complete authorization for access to genetic resources.

For foreign researchers, they need to identify those benefits that their research and program brings to Kenya, including training and resources provided to their Kenyan counterparts.

The OP/NCST Process has the ability to get a provisional permit from the OP, or more often from the Ministry of Education, on behalf of the OP. Requirements for a provisional permit include the submission of a research proposal, payment of administrative fee and the identification of a Kenyan partner, institution or sponsor. Provisional permit holders are allowed to conduct research pending issuance of final permits. Once a provisional permit has been given, the application is forwarded to NSCT for review. NCST gives the final approval. Provisional permits raise a question on the possibility of creating a loophole where collecting and exporting genetic resources could occur under a provisional permit that was not going to be given final approval.

Once a researcher has the permit from the OP, if the project includes collecting genetic resources from certain areas or collections, additional authorizations from other agencies may be required. For example, for any collection in protected areas, there is an additional obligation to get a permit from the Kenya Wildlife Service. This obligation and most of the others, pre-dated CBD. KWS's exclusive authority over protected areas dates back to the post-independence Wildlife Department and its stewardship of Kenyan genetic resources in these areas was reiterated in the 1999 EMCA Law.

Finally, even with the research permit and the collecting permit, a researcher also needs an export permit for specimens.

Local Counterparts

The main institutions dealing with genetic resources at the domestic level are the institutions that make up the National Research System, the universities, the National Museum of Kenya, and the many government research institutes. Kenya also houses a number of important international research organizations such as ICIPE and IPRI. One of these institutions is the Kenyan Agricultural Reseach Institute (KARI). While KARI has developed some products based on the collection of germplasm from Kenya, it has also made extensive use of the collection of the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). In turn, Kenya has made its national collection of germplasm openly available to CGIAR and other countries. Ownership of this germplasm, and in particular developed and improved genetic resource-based products and processes, requires intervention. The best intervention in this case will be an internationally binding disclosure requirement, which will ensure access and benefit sharing arrangement including a technology transfer mechanism.

Property Rights Issues

The IPR obligations are met through collaborative efforts of KIPI (for Industrial Property issues) and KEPHIS (which has a mandate including Plant Variety Protection and quarantine).

National bio-safety committee, co-coordinated by the NSCT, with membership from KIPI, KEPHIS, and the National Agricultural Research Institutions among others, and in particular KARI, play a major role in environmental regulation with their mandates including matters of technology development and transfer.

Plant Variety Protection (UPOV -1978 / UPOV-1991)

Kenya enacted the Seeds and Plant Varieties Act Cap 326 in 1977, providing for the protection of plant breeders rights. The 1977 Act (reviewed in 1991) and the 1994 regulations, broadly comply with the provisions of UPOV 1978 convention. Kenya became a party to UPOV 1978 convention in April 2000. The parent legislation and the implementing regulations are both being revised. It is expected that these will include some features of UPOV 1991.

The Act has no specific provisions addressing the question of farmers' rights. The 2001 draft bill does not contain provisions reflecting those of UPOV 1991, however, as these provisions still prohibit the exchange of seed among farmers, and thus fall far short of the realization of farmers' rights (control of wheat seed and cut flowers case in Kenya is of relevance).

Kenya provides for protection of plant varieties by an effective sui-generis *system under provisions of the UPOV convention. Microorganisms and microbiological processes and products, are all subject to patent protection. The current legislation is being reviewed to address issues and interests of indigenous communities and small-scale farmers as stipulated in UPOV 1991 and the domestication of the ITPGFIA, where farmers' rights are addressed. Amendment of Art. 29 of TRIPS, to demand for disclosure and production of certificates of origin in all IP application on products and processes based on genetic resources is recommended. This would be a solution for monitoring and the distribution of benefits, through royalties and other contractual benefits arrangements.*

National Patent Legislation

The main challenges to address in the creation of an effective International Regime is in this paper's view, a legally-binding instrument necessary in order for States to codify sovereign rights over its genetic resources. Kenya has been a member of WTO since 1995, and has made its patent law TRIPS compliant. It supports the developing country position on the relationship between WIPO (IP Treaties) and the CBD, arguing that there are cross cutting issues that should be resolved. An interesting case of reference is the IP related ABS case involving *Extremophiles* in a patent protected technology in the detergent and textile industry.

Plant parts or bio-technological processes and products (micro-organisms and micro-biological processes and products) are patentable as provided for under Section 26 of Industrial Property Act –2001, but exclude plants from patent ability. The possible way plants and plant parts can be refused protection would be on grounds of public morality, public health and safety, or humanity and environmental conservation. In this case, a Patent and PVP system, with a role for trademarks, certification marks and appellation of origin, will be the most mutually beneficial approach. This makes it ideal to protect and provide evidence for benefit sharing, should IP documents disclose countries of origin.

Potential Solutions

R & D Institutions and IP Management

Genetic resource based R&D activities of public institutions in Kenya are carried out by the national research system, foreign research institutions and international research institutions. For them to access and develop Genetic Resource based processes and products, it is recommended that a legally binding *sui-generis* system for Genetic Resources (GR) and Traditional Knowledge (TK), where CBD and WIPO IP treaties are mutually supportive, be adopted. This will help to address bio-piracy that is due to National legislations missing complete and functioning elements because of an absence of a legally binding Disclosure of Country of Origin requirement in IP application. Disclosure of Country of Origin could fill the gap in the ABS system in IP applications and Amendment of TRIPS Art.29, to require the same.

Recommendations

Genetic resources acquired prior to CBD are to be given same IP disclosure requirements, similar to post CBD accessions. This should not be voluntary, but mandatory, for IPR purposes. Genetic material accessed for research purposes only should not be transferred to third parties, without safeguards to assure that the non-commercial nature of the original transfer is maintained. If this material is requested to be used for commercial research, it should not be transferred until there is a agreement of mutually agreed terms with the appropriate Kenyan authorities.

It is also recommended that processing of IPR applications be on condition of legally obtained GR, accompanied by any restrictions under which the material was obtained.

Conclusion

Kenya takes note of the report of the IGC and appreciates the work being done by the committee on WO/GA/31/8 matters concerning intellectual property and genetic resources traditional knowledge and folklore and invitation made by CBD-COP 7 and in particular Decision VII/19 because it touches on issues within WIPO mandate. The issues raised in the invitation are relevant to the work of the intergovernmental committee and several other WIPO processes.

On the methodology, it believes that the issues raised touches on the work of various processes and committees under WIPO including the IGC, CBD and WIPO secretariats, who, in collaboration with WTO, should identify the various processes and relevant committees to expedite the tasks anticipated by the invitation.

DISCUSSION PAPER

The International Regime. A Missing Element

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Introduction

Despite Terms of Reference (TOR) for the negotiation of an international regime being established by COP Decision VII/19 there is no consensus on what the regime may involve. This paper seeks to identify important elements missing from current arrangements.

The International Regime (IR)

The first point to make about the Terms of Reference for the negotiation of the IR is that it reflects that much of the regime already exists. The 16 bodies listed under 'Relevant elements of existing instruments and processes' show this.[2] From this list it is clear that much of the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing will be taken up with understanding the role and contribution of these instruments and processes and what is required to make them work better together, without duplication, or conflict. This same process needs to examine gaps and how they may be filled. Happily the TOR recognizes this under 'Process'.

However, a key element in the consideration of an international regime on genetic resources is missing. This is the means whereby companies, researchers and other organizations with a stake in the biodiscovery process can demonstrate their adherence to standards of conduct that show they are complying with both the spirit and letter of the CBD. With so many steps involved in the value chain, from initial collection to final product or innovation, the number of 'players' and transactions involved is inevitably large, diverse, and often invisible to third parties. There are a number of ways to respond to this reality. Transparency within the Intellectual Property system through disclosure in patent applications of information about the source of genetic material used to develop a product or innovation is an example of such a response. Another is to create a tracking system to follow material taken and its subsequent development through the value chain via certificates of origin and the use of unique identifiers.

Industry Compliance

While regulatory debates focus on the development and application of legal rules and requirements the use of voluntary measures is often down-played in the common belief that financial gain will lead organizations to non-adherence or an unwillingness to submit to external scrutiny.

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[1] The views expressed in this paper are those of the author and do not necessarily represent those of the Australian Department of the Environment and Heritage.

[2] See VII/A9 Annex 'Terms Of Reference For The Ad Hoc Open-Ended Working Group On Access and Benefit-Sharing' para (d) xxiii.

In the field of biodiscovery a system of compliance with industry best practice standards can be a useful mechanism to establish industry normative behaviour, thereby significantly reducing the regulatory burden on resource providers.

Advantages of Industry Standards

There are a number of reasons why such a system would be attractive generally, and attractive in particular, to industry. They include:

- Establishing the reputation of the company by demonstrating a commitment to good faith conducts;
- Establishing minimum criteria for resource providers in deciding with which organizations to enter into benefit-sharing relationships;
- Establishing a minimum criterion for public research organizations when making decisions about entering into collaborative partnerships with commercial bodies;
- Assisting capital providers when determining issues of commercial and legal liability risk;
- Enabling companies to know what is expected of them, especially valuable for small start-up biotechnology companies;
- Enabling companies to get non-confrontational feedback about their practices.
- Assisting companies in continual improvement;
- Assisting potential shareholders in making investment decisions;
- Assisting institutional investors in forming judgments about the company or organization;
- Becoming a minimum criterion for ethical investment funds;
- Becoming a vehicle for raising standards of industry conduct as regulatory requirements change;
- Becoming a source of feedback to resource providers and regulators, and
- Identifying companies who do not meet standards to regulators, genetic resource providers, competitors, shareholders and capital providers.

The most significant benefit would be, however, to reduce mutual suspicion between resource providers and industry and by so doing, stimulate investment in natural product biodiscovery. For this reason alone, an industry standards system warrants inclusion in the development of an international regime.

DISCUSSION PAPER

Nature of an International ABS Regime

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The CBD-COP7 decision provides for the international ABS regime to consist of a wide range of possible elements across an extensive list of international instruments and processes.

The World Summit on Sustainable Development plan of action called for the negotiation of an international regime under the Convention on Biological Diversity. Therefore, central to the development of an international regime are the three CBD objectives. Accordingly, a fundamental objective of access and benefit-sharing from the use of genetic resources is to support conservation and sustainable use of biodiversity, in particular *in situ* conservation/sustainable use of species and ecosystems.

The cornerstone concept underlying the international ABS regime can be found in CBD, namely that states have sovereign rights over their own biological/genetic resources. Under CBD Article 15, access is to be facilitated and access is to be provided based on prior informed consent and benefit-sharing negotiated through mutually-agreed terms.

Although traditional knowledge was not included within the scope of CBD Article 15 (Access to Genetic Resources), it is now clearly within the scope of the negotiations on an international ABS regime. My understanding is that some countries included access and benefit-sharing aspects of CBD Article 8(j) in their national ABS laws and then subsequently negotiated the expansion of the scope to include both genetic resources and associated traditional knowledge into the voluntary CBD Bonn Guidelines and the CBD COP7 decision to negotiate an international ABS regime.

Not unlike the CBD, the international regime may include wide-ranging objectives that seek to attain, *inter alia*, environmental, innovation, trade, investment, equity, scientific, development, social and cultural outcomes.

Ultimately, the regime will first and foremost manifest itself as environmental protection/regulation in order to ensure conservation and sustainable use of genetic resources. In the longer term, the most important aspect of access is not facilitated access (i.e. efficient prior informed consent regulations) but rather ensuring access to genetic species into the future through measures to conserve and sustainably use in-situ species and their associated ecosystems. There is no access when species and ecosystems are lost forever. This is a concern for both users and providers of genetic resources.

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[1] The views expressed are solely those of the author.

It is clear that developing the market institutions (e.g. property rights, regulatory instruments) and providing economic policy incentives to assist in the creation and growth of markets for genetic resources alone cannot be a panacea for reversing the rate of loss of species and ecosystems. Other government action will be needed.

One strategy may be to create national parks or other wild spaces that will be protected from logging, agricultural expansion and urban sprawl so that species will be available for research by future generations. The establishment of protected areas in developing countries in support of retaining unique ecosystems for ABS purposes will likely require the infusion of significant new financial support and capacity-building by developed countries, consistent with the WSSD Plan of Action on Biodiversity (para. 44).

Alternatively, in certain cases it may be feasible to integrate ABS policy into resource/landscape management; for example, a survey of the unique ecosystems/genetic resources and biodiversity which has been traditionally-used by indigenous and local communities could be incorporated into forestry management plans so as to preserve species for future biotechnology research.

The principle point is that conservation-based environmental measures will be essential to achieve the economic and trade objectives of the international ABS regime and conversely ABS policy will need to be integrated into national protected areas and landscape/resource management strategies.

Potential CBD Protocol on ABS?

If countries were to agree to negotiate an ABS protocol under the CBD this instrument would undoubtedly establish the marketplace rules to govern investment, commercialization and trade in *in situ* biological/genetic resources. This hybrid instrument would include elements borrowed from, *inter alia*, multi-lateral environmental agreements, trade agreements and intellectual property treaties.

The key trade-off in the negotiation may revolve around access and benefit-sharing. Going beyond facilitated access and transparency under the CBD Bonn Guidelines, there will be pressures to include national treatment and investment provisions consistent with basic trade principles. In return, there will be pressures for all countries to adopt national "user" measures to recognize and enforce property rights of other countries.

Another key issue in the negotiation of such a protocol would be the national-level prior informed consent procedures for accessing genetic resources as compared to the community-level PIC procedures for accessing traditional knowledge and related genetic resources. In effect, the protocol may contain provisions related to two separate *sui generis* access/property regimes.

Another important negotiation could revolve around the nature of property rights created for genetic resources and traditional knowledge under such a protocol; would these rights be real property, intangible property, information property or intellectual property? Civil Code, common law and customary law differences in property rights concepts will likely rise to the forefront of discussions.

Any monitoring/enforcement could contain elements of both property rights and environmental regulation. For example, there may be aspects that can be adapted from the certificate system under CITES which governs trade in endangered species and includes export permits, import permits, border measures and enforcement in the marketplace.

Potential Evolution of a Potential CBD Instrument

The development of a potential CBD instrument could occur in stages. One potential evolution of an instrument is presented below in order to encourage discussion as to how such an instrument might evolve over time.

The negotiation of a CBD protocol on ABS could initially focus on a declaration to reinforce that States have sovereign rights over their own genetic resources and that Parties agree to adopt legal measures in support of the basic ethical principle that one should not profit in one country from undertaking illegal activities (i.e. unauthorized access and export of genetic resources) in another country. Such a declaration would need to be drafted in such a way to allow some national flexibility to determine how to implement under both civil and common law systems.

Perhaps a second stage could be the negotiation of a protocol under CBD which would seek to establish minimum standards and enforcement. Goals of such a protocol could be to harmonize national laws along the lines of the voluntary Bonn Guidelines, to encourage other countries to enact national ABS laws and to promote the adoption of "user" measures. Such an instrument could resemble WIPO treaties such as the Paris Convention (Industrial Property) and the Berne Convention (Copyrights) where minimum standards are established but there is a significant degree of flexibility for countries to implement the Conventions based on national circumstances. These Conventions allowed flexibility since generally there was a lack of redress for Parties where there was non-compliance. An element of UPOV that could be adapted to ABS is the UPOV reciprocity requirements whereby access to new plant varieties is restricted to nationals of countries that have ratified UPOV under national law. Such reciprocity may be important for encouraging some countries to ratify the protocol.

Such a protocol could also be evolutionary like UPOV and some WIPO treaties which have different negotiated levels of standards over time (e.g. UPOV 1978 and UPOV 1991). Dispute mechanisms could be a later element included in a phased approach to a protocol. Generally, multi-level treaties also have the benefit of creating an incentive for laggard countries to ratify at the lower level of obligations in advance of the coming into force of the higher standard.

DISCUSSION PAPER

Towards an International Regime that Stresses Infrastructural Capacity Development in the Source Countries as a Key Factor for Effective Access and Benefit Sharing in Bioprospecting

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Introduction

The Convention on Biological Diversity (CBD) has three main objectives, and these are:

- The conservation of biological diversity;
- The sustainable use of its components; and
- The fair and equitable sharing of benefits arising out of the utilization of genetic resources, including appropriate access to genetic resources, appropriate transfer of relevant technologies (taking into account all rights over those resources and to technologies) and appropriate funding.

Articles 16 and 18 of the Convention deal with access to and transfer of technology and technical and scientific cooperation respectively. The importance that the international community attaches to these aspects of the convention cannot be overstressed. The first meeting of the COP, in decision I/2, decided that "in accordance with Article 16 of the Convention, and to meet the objectives of conservation of biological diversity and sustainable use of its components, projects which promote access to, transfer of and co-operation for joint development of technology" would be one of the programme priorities for access to and utilization of the financial resources available through the Convention's financial mechanism. Article 18 further stresses that in promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

Just as one objective of the convention is of no greater importance than any other, and since each is in fact dependent upon the other, it is also important to note that the fair and equitable sharing of benefits arising out of the utilization of genetic resources are intrinsically linked to access to those genetic resources, appropriate transfer of relevant technologies (taking into account all rights over those resources and to technologies) and appropriate funding. Categories of technologies are defined as: technologies relevant to the conservation of biological diversity; technologies relevant to the sustainable use of the components of biological diversity; and those technologies that make use of genetic resources.

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[1] Opinions expressed in this paper are those of the author and do not necessarily reflect those of BDCPC.

Importance of Infrastructural Capacity Development in the Source Countries

The importance of the development of infrastructural capacity in the source countries can be summarized in four points as follows:

Infrastructural Capacity Enables In Situ Research on 'Orphan Diseases'

Experience has shown that most research carried out on diseases that affect people is done so in developed countries for the simple reason that the chances of reaping back the enormous investment in R&D process are higher in those countries than in poor source countries. This, in effect, means that some diseases that are limited to poor source countries (what we have termed here as orphan diseases), and are a priority of those same countries, receive less attention. If these countries have the necessary infrastructures they will be able to carry out research on these diseases for the benefit of their populations. The time has now come when the average local person will want to see collaborative research come out of laboratories and affect their livelihood in a significant way.

Infrastructural Capacity to Make Use of Preliminary Collaborative Research Findings

In collaborative bioprospecting research, one of the benefits is access to preliminary research results. These preliminary results usually indicate the level of activity of compounds from the plant samples which are sent back to the collaborative source country institutions. The challenge, however, arises when the developed country partners decide to discontinue further research on those compounds and the developing country partner is left with no means to move on because they lack the infrastructure and resources necessary. With a viable infrastructure, they can either continue with the same research or use such preliminary results to carry out research related to other diseases.

Infrastructural Capacity Gives Power to Negotiate

There is nothing as salient in collaborative bioprospecting ventures as the power to negotiate. For benefit-sharing to be fair and equitable, each party must be able to negotiate that effectively from the onset. Experience has shown that competition for the limited funds that the developed countries are willing to spend on R&D has been aggravated by limited infrastructural capacity, thus reducing some of the source country scientists to mere collectors. With good infrastructure, these well trained source country scientists can negotiate with their partners on equal basis and this in effect will lead to effective negotiation of benefits sharing terms that are fair an equitable.

Infrastructural Capacity Out-Lives the Project

Many development projects in Africa have been criticized for their top-down nature, designed to survive only as long as foreign sources of funds are available. We have seen projects that dramatically and positively change the economic, social and cultural landscape of local communities overnight, only to leave those very communities worse off after foreign partners come to the end of their funding period. It is not uncommon to hear of local people say that when this or that project was going on, they benefited from payments as collectors or guides, received good prices for their agricultural projects, and now that the project has ended they do not receive such benefits.

The response would be different if, during the project execution phase, there was significant infrastructural development tailored to meet the needs of the people allowing them to continue working even when their foreign partners have left.

The Way Forward

Moving From Quick Fixes To Felt Needs

As noted earlier, the Convention explicitly recognizes the role that all categories of technology play in the conservation of biological diversity and the use of genetic resources. Article 12 focuses on research and training, which is an essential aspect of technological capacity-building. It calls on the Contracting Parties to "establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the *specific needs of developing countries*". The question that immediately comes to mind is who determines the needs of those developing country parties? Is it the technology suppliers who determine what the developing countries need and which they (the developed countries) are willing to supply or is it the developing countries that determine what they need and are willing to apply? At this point, we will now have to look at the concepts of Quick-Fix and that of Felt Needs.

Quick Fix Illusion

John M. Perkins, founder and publisher of *Urban Family* magazine, says the Quick-Fix solution sets up a "we-them" dynamic or "we do-gooders have the solution for these poor people".[2] In our present case, such an attitude assumes that despite not living in or having a good understanding of developing source countries, these people believe they know what such places are in need of. As has been realized, one of the main limitations of current discussions on the access to and transfer of technology is that they treat all technologies as having the same characteristics and as being suitable for transfer through one mechanism. The characteristics of a particular technology not only determine the mechanism or ways for its transfer, but are also likely to influence the kinds of policies that are put in place to promote its development and transfer. Thus, it is important to understand the nature or characteristics of the relevant technologies before determining specific mechanisms and measures to facilitate their development and/or transfer.[3]

The Quick-Fix illusion is therefore applicable when we assume that we already know what some one needs, we know the solution and the expected results, i.e. we know what needs fixing. In so doing we will also like to shape the person with our values, doctrines etc. The quick-fix mentality makes the technology suppliers to hurriedly focus on the wrong technology that they presume is required and overlook what is most needed. Until contracting parties truly interact with each other on a partnership basis, listening and appreciating each other's opinion and feel the needs of others with them, technology transfer will only be scratching the surface of yet unsolved real problems. Perkins says further that the great question in indigenous leadership development is "How do we affirm the dignity of people, motivate them, and help them take responsibility for their own lives?" When answering this key question, we face the problem associated with the Felt-Need Concept.

The Felt Need Concept

Felt needs are different from person to person and from place to place. For effective co-operation to take place these needs have to be identified. The only way to identify these needs is to enter into a true partnership with people and true partnership can only exist when each party feels significant and important and as having something to offer to the relationship. Most African scientists have had training in universities in developed countries, often the same universities as their developed countries colleagues. Due to an acute lack of infrastructure and research funds from their governments and private investors, however, they cannot conduct as much research as these colleagues. They have the task of balancing conservation with the felt development needs of their people. No one can pretend to know the needs of the local people more than these people who are part of the same society and feel the needs themselves. If by entering into a partnership arrangement with their developing country partners, northern partners have an upper hand in decision making on all research matters, simply because they have access to better infrastructure and funding. Such a situation will be ushering in a quick-fix syndrome which might not last.

The effective involvement of source country scientists in research builds bridges of trust to combat distrust and suspicion that have always separated the rich from the poor. This relationship also motivates developing country partners to take responsibilities for their own lives. It is the opposite of the welfare mentality, which cripples people and makes them dependent on others.

Sustainable Infrastructure Development Approach

Building on the base of national experts that developing countries have, there is a need for what has been called the turnkey-projects approach, which is a mode of transferring certain components and elements of technology under bilateral technical-cooperation arrangements. It involves the construction, demonstrated operation, and commissioning or handover of a facility by technical experts from a technology-supplying firm and/or country to the recipient institution or country. This mechanism has been applied in the development of gene-banking facilities and in the transfer of relevant technology elements in a number of developing countries. This will however also depend on the developing countries governments to create enabling socio political and legislative environment, which assures security for investment.

There is also a need for greater public investment in infrastructure for effective research at the national level. Generally, potential benefits of bioprospecting are usually 15 long years down the road and private investment is usually very limited. Source country governments need to invest more in this area if they want to negotiate from the position of strength for their benefits.

Conclusion

The Rio Summit is 12 years old and with the experience the international community has gathered over these years we cannot overlook the importance of infrastructural development in source countries for the fair and equitable sharing of benefits. R&D collaboration should be based on the fact that each and every party has something to offer and that source countries have the human capacity and are able to determine what their needs are and that what they lack is the necessary infrastructure. Instead of coming with a quick-fix solution, research partners should try to develop a true collaborative relationship through a felt needs approach. An international regime that stresses this factor will be the desire of most source countries.

DISCUSSION PAPER

A few thoughts on the international regime and provider / user measures

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The International Regime

The overall goal of an International Regime on access and benefit-sharing (ABS) should be to simplify and increase the transparency of international transactions related to genetic resources and associated traditional knowledge (TK), and therefore to help deliver the third objective of the Convention on Biological Diversity (CBD).

To this end, two types of measures could be considered: those that facilitate access for environmentally sound uses and measures that ensure the fair and equitable sharing of benefits. In international negotiations, these measures are often called 'provider measures' and 'user measures'. This terminology is however not accurate. Measures that facilitate access can also be taken by users whilst measures that ensure benefit sharing can be taken by providers. The Bonn Guidelines have already cast some light on what the above measures could be. The Guidelines will be an essential component of the international regime.

In relation to access, the development of clear, non-discriminatory national frameworks is essential. Minimum standards could be established. For instance, there should be a one-stop shop for those who require access to genetic resources: e.g. through one national competent authority and/or focal point. National measures should also include consultation mechanisms that would require the prior informed consent of indigenous communities before genetic resources and associated TK they hold can be accessed. The advertising of such national arrangements would also be important to raise awareness of those who seek access to genetic resources. One possibility in this respect is to include specific paragraphs in the customs declaration.

National ABS frameworks only exist so far in a limited number of countries and present limitations. Most of them predate the Bonn Guidelines and there is limited evidence that a serious effort to revise them has taken place since COP 6. A considerable effort in capacity building would be necessary to help developing countries put in place appropriate national regimes. Therefore, capacity building will be an essential element of the international regime. Financial resources to this end could be found through a combination of public and private funds. In addition to GEF and bilateral development cooperation, one could think of private funds coming from companies that have a keen interest in bio-prospecting activities. Partnerships in this respect could be sought.

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[1] The views expressed here are the author's only and do not reflect the point of view of the European Commission.

In relation to ensuring benefit sharing, a number of measures at national/regional/international level could be envisaged. These measures could include a combination of voluntary and binding instruments. The limited experience gained in the implementation of the Bonn Guidelines in Europe has certainly shown a surprising low level of awareness of CBD rules among some stakeholders, particularly in the private sector. More efforts are necessary for the development of institutional policies, codes of conduct and corporate policies that would, for instance, introduce the use of material transfer agreements as a standard practice. The development of regional networks of ABS focal points, the use of Clearing House Mechanisms and the use of Corporate Social Responsibility processes are all tools to explore in this respect. Moreover, the potential of voluntary certification schemes, such as ISO 14001 or the stricter EU EMAS scheme should not be neglected. These measures could be promoted by countries as incentives for compliance.

Measures at the national level are necessary but will not be sufficient to achieve the above-mentioned objective of an international ABS regime. In particular, they do not address the main challenges of an international regime: they are not enough to track the genetic resources and TK across jurisdictions nor they offer a possibility of claiming benefit sharing in other jurisdictions. Therefore some international tools need also to be envisaged.

These could include measures in relation to intellectual property rights (IPRs) such as disclosure of origin in IPRs applications. It needs to be stressed that only some genetic resources and associated TK are used for inventions that are protected by patents or other intellectual property rights like plant variety rights. Therefore, measures such as disclosure of origin could only be one type of a wider range of measures that altogether could contribute to ensure benefit sharing. The issue of a disclosure requirement in patent applications has been the subject of hot debate for a few years now in many fora including the CBD, WIPO and TRIPs. A disclosure requirement for patent applicants could indeed be of help to increase the transparency of international transactions related to genetic resources. However, it will be essential to frame such a requirement in a way that it does not discourage innovation therefore causing a lose-lose situation where the sustainable use of genetic resources is discouraged and benefits are not generated. Moreover, it will also be necessary to achieve an international agreement on a disclosure requirement in order to try and preserve a level playing field among different parts of the private sectors in the different parts of the world.

The ongoing discussions in WIPO offer, at least in the short term, the most obvious road ahead to achieve such an international agreement. An international disclosure requirement should be an important component of the international regime on ABS. Should such a global agreement prove to be impossible to achieve in the present political situation, it would be important for individual or groups of countries who favour such a requirement to consider implementing it unilaterally showing that it can work in practice.

Also in WIPO, the development of an international *sui generis* system for the protection of TK is also an important tool to ensure its respect and preservation. Such a system should be compatible with the customary law of indigenous peoples: it could actually focus on the recognition of such laws and should constitute an essential element of the international regime. Other systems of protection outside patent law could originate from the work of the CBD Art. 8j) group. However, it will be necessary to ensure the complementarity of the outcomes of the work of WIPO and of the latter group.

Finally and importantly, another measure at the international level that could help ensuring that benefit sharing takes place is the so called certificate of origin/legal provenance. An internationally recognized certificate could accompany the genetic resources and associated TK throughout the chain of transactions that ultimately generate benefits thus bringing more transparency into the system. There are many issues related to the practicability of such a certificate that need to be addressed.

What would be its relationship with Material Transfer Agreements? Would it be additional or would it replace them? Is it possible to develop a one fit all international certificate that would be utilized for all uses and all types of genetic resources? Should it be limited to a template? How would it apply to pre-CBD resources for which there is no benefit sharing obligations and to post-CBD but pre-certificate resources?

If an internationally agreed certificate of origin existed, it could be 'enforceable' across the jurisdictions in which it is recognized. Through a system of mutual recognition, it would, in fact, be possible to open up access to justice for the countries of origin of genetic resources in the countries were the users are located. Existing international civil liability regimes could be inspirational in this respect.

In relation to arbitration, when genetic resources have been the subject of a contract, that contract could provide for arbitration as a means to quickly solve possible disputes. Parties to the contract could resort to the arbitrator of their choice, e.g. the Permanent Court of Arbitration.

Section III: Specific Issues for Consideration in the Elaboration osthe International Regime

A:Interface with Existing IP System & Limits and Opportunities for Existing IP Rights.

Disclosure of the Source of Genetic Resources and Traditional Knowledge in Patent Applications

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Introduction

The Terms of Reference for the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing (ABS-Working Group) adopted by the seventh Conference of the Parties (COP-7) of the Convention on Biological Diversity (CBD) list, as one element to be considered by this working group for inclusion in the international regime, the "disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights".[1] Besides the CBD, other international fora are currently considering such disclosure requirements, namely the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Disclosure measures are seen as increasing transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization, in particular with regard to the obligations of the users of such resources and knowledge.[2]

When introducing a disclosure requirement in patent law, a number of issues arise, including the following: What terminology should be used? Should one speak about "genetic resources", "biological resources" or "biological material", and about "traditional knowledge" or "knowledge, innovations and practices of indigenous and local communities"? What information needs to be disclosed in the patent application? Is it the "source," the "country of origin" or the "geographic origin"? When does a disclosure have to be made, that is, what mechanism triggers the requirement? Are there any exceptions to the requirement? In what international instrument should the requirement be introduced? Is the requirement of a formal or of a substantive nature? Should it be optional or mandatory for States to implement the requirement at the national level? Should the wrongful disclosure or failure to disclose carry any sanctions and, if so, what kind? And finally, what existing international law[3] needs to be taken into account?

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[1] See Decision VII/19, *Access and benefit-sharing as related to genetic resources (Article 15)*, Section D, Annex, subpara. (d)(xiv).

[2] With this policy objective, disclosure requirements can be seen as measures which (at least indirectly):
- "promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources" (*id.*, subpara. [d][v]);
- "ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity" (*id.*, subpara. [d][ix]); and
- "ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j)" (*id.*, subpara. [d][x]).

According to the Terms of Reference, these measures shall be considered by the ABS-Working Group for inclusion in the international regime.

[3] This concerns namely the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT) of WIPO, the TRIPS Agreement, the CBD, and the International Treaty on Plant Genetic Resources for Food and Agriculture of FAO (FAO-IT).

This paper briefly analyses these issues and contains the author's proposals for the way forward with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications.[4]

Genetic Resources and Traditional Knowledge

The disclosure requirement should mirror the terminology used in the international fora and agreements relevant to access and benefit-sharing:

- *Genetic resources*: The CBD and the Bonn Guidelines refer to "genetic resources," while the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO-IT) refers to "plant genetic resources for food and agriculture" (PGRFA).[5] The respective definitions of these terms are largely synonymous.[6]
- *Traditional knowledge*: The use of terms in the relevant international fora is not uniform;[7] nevertheless, all terms used are presumably synonymous with the term "traditional knowledge".[8] Being a measure to be taken under patent law, the disclosure requirement focuses on traditional knowledge that can give rise to a technical invention. Furthermore, the traditional knowledge in question must be related to or associated with genetic resources. It thus seems best to use either the term "traditional knowledge related to genetic resources" or "traditional knowledge associated with genetic resources."

The Concept of the "Source"

According to both the CBD (see Arts. 15.4 and 15.7) and the Bonn Guidelines (see paras. 17, 18, 28, 31, 32 and 48), a multitude of entities may be involved in access and benefit sharing with regard to genetic resources. The same applies with regard to PGRFA under the FAO-IT (see Arts. 9.2(b), 12.2,

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[4] For a more detailed analysis of these issues see: Girsberger, M.A., 2004. *Transparency Measures Under Patent Law Regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit Sharing*, Journal of World Intellectual Property, Vol. 7 No. 4, July 2004, pp. 451-489.

[5] See Art. 15 of the CBD, paras. 22 to 50 of the Bonn Guidelines, and Arts. 10 to 13 of the FAO-IT.

[6] See Art. 2 the CBD and Art. 2 of the FAO-IT.

[7] The FAO-IT, the WTO and WIPO uniformly use the term "traditional knowledge." In contrast, the CBD, the various CBD-fora and the Bonn Guidelines use different terms interchangeably. These include "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"; "traditional knowledge"; "associated traditional knowledge, innovations and practices"; "knowledge, innovations and practices of indigenous and local communities"; and "traditional knowledge, innovations and practices associated with genetic resources."

[8] The Secretariat of WIPO defines "traditional knowledge" as "knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or indigenous culture or community which preserves and transmits it between generations;
- linked to a local or indigenous community or other group of persons identifying with a traditional culture through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive, a relationship that may be expressed formally or informally by customary law;
- knowledge in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts, and
- identified by the community or other group as being traditional knowledge."

(WIPO-IGC, 2003: *Overview of the Activities and Outcomes of the Intergovernmental Committee*, WIPO-document WIPO/GRTKF/IC/5/12 [3 April 2003], para. 45. See: http://www.wipo.int/documents/en/meetings/2003/igc/pdf/grtkf_ic_5_12.pdf).

12.3(e)-(h), 13.2(d)(ii) and 13.3). Parallel to genetic resources, the CBD (see Art. 8(j)) and the Bonn Guidelines (see paras. 31 and 48) allow for a multitude of entities to be involved in access and benefit sharing with regard to traditional knowledge, including primarily indigenous and local communities.

The disclosure requirement should reflect the multitude of entities that may be involved in access and benefit sharing. General terms, namely "source" and "origin," thus serve best the purposes of this requirement. "Origin," however, is contained in other terms of relevance with regard to genetic resources, in particular in "country of origin" and "geographic origin" and may be confused with these terms. Furthermore, the term "geographic origin" lacks an international definition. Additionally, both "country of origin" and "geographic origin" may be difficult or impossible to determine in practice. And finally, both concepts are much too restrictive to fully take into account the multitude of entities that may according to the CBD, the Bonn Guidelines and the FAO-IT be involved in access and benefit sharing. As a result, "source" seems to be clearly in the foreground to be used in the context of the disclosure requirement.

The term "source" should be understood in a broad sense to cover all potential "sources" of genetic resources and traditional knowledge allowed for in the CBD, the Bonn Guidelines and the FAO-IT. Based on these international instruments, the entity competent (1) to grant access to genetic resources and traditional knowledge, and/or (2) to participate in the sharing of the benefits arising out of their utilization, is in the foreground to be declared as the source. Depending on the genetic resource or traditional knowledge in question, one can distinguish between "primary" and "secondary" such sources: Primary sources are the Contracting Party providing genetic resources (see Arts. 15, 16 and 19 of the CBD), indigenous and local communities (see Art. 8(j) of the CBD), and the Multilateral System established by the FAO-IT (see Arts. 10-13); secondary sources are *ex situ* collections such as gene banks and botanical gardens, databases on genetic resources and traditional knowledge, and scientific literature.

Accordingly, there is what can be termed a "cascade" of possible primary and secondary sources: Patent applicants must disclose the primary source to fulfill the disclosure requirement, if they have information about this primary source at hand. A secondary source may only be disclosed if patent applicants have no information at hand about the primary source. Only if the patent applicant (or the inventor) has no information at hand about the primary or the secondary source, may he disclose that such source is unknown.

Considering the broad understanding of the term "source", cases where no primary or secondary source is known are likely to be rare. Nevertheless, cases are possible where patent applicants, for reasons beyond their control, do not have the necessary information to fulfill the disclosure requirement. An example at hand is a plant stored in a gene bank, which was collected decades ago, and for which no information about its source exists. For reasons of legal certainty and of fairness, patent applicants should in such cases be able to declare that they do not have the necessary information (i.e., the source is unknown to the inventor or the patent applicant) and fulfill the disclosure requirement accordingly. Otherwise, they would be forced to either wrongfully disclose the source or to forego patent protection.

Mechanism "Triggering" Disclosure Requirement

With regard to genetic resources, an invention should be directly based on a genetic resource to which the inventor has had access in order for the disclosure requirement to apply. Accordingly, the invention must make immediate use of the genetic resource, that is, depend on the specific properties of this resource, and the inventor must have had physical access to this resource, that is, at least sufficient enough contact to identify the properties of the genetic resource relevant for the invention. With regard to traditional knowledge, the inventor should know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

Legal Basis of Disclosure Requirement

Generally, the requirements with regard to patent applications can be categorized as follows:

- *formal requirements* which are examined for the purposes of determining if a complete application has been filed;
- *formal requirements strongly linked to substance* concerning the various parts of the patent application for the purposes of search, examination and grant, that is, requirements which could affect the scope of a search or result in the rejection of the claims during the substantive examination of the patent application, and
- *substantive requirements*, under which the claims are evaluated for patentability, namely, definition of prior art, disclosure of the claimed invention, patentable subject matter, novelty, inventive step and industrial utility.

The policy objective of the disclosure of the source is to increase transparency in the context of access and benefit sharing. Accordingly, this requirement is examined for the purposes of determining if a complete patent application has been filed; it is thus linked neither to the search, examination or grant of patents, nor to the evaluation of the claims for patentability. As a result, it has to be considered as a formal requirement, not a formal requirement strongly linked to substance or a substantive requirement.

Being of a formal nature, Article 27(1) of the PCT and Rule 4.1 of the PCT-Regulations as well as Article 6(1) of the PLT apply. At present, neither Rule 4 nor Rule 51*bis*.1 of the PCT-Regulations contain provisions on the disclosure requirement. Accordingly, in order to clarify the legal situation at the international level, it appears necessary to amend the PCT-Regulations and thereby explicitly enable the national legislator to introduce such a measure. Moreover, it is necessary to take into account Article 62.1 of the TRIPS Agreement, which states that Members of the WTO may only require "reasonable" procedures and formalities as a condition of the acquisition or maintenance of patents.

Optional vs. Mandatory Introduction at National Level

Considering the state of play at the international level and the opinions expressed by the various stakeholders, it seems advisable to go for an optional solution (an "enabling clause" in the relevant international agreement) at this point in time, granting those States willing to act at the national level the possibility to do so, without, however, preempting the results of future international discussions on the issue. Furthermore, an optional solution would most likely be found more easily than a mandatory one, and could thus be realized in less time. Additionally, it would allow governments and the international community to gain experience with the disclosure requirement, without prejudice to further international efforts.

Opting for a mandatory solution would indeed ensure that all States, which are a Contracting Party to the chosen international instrument, are obliged to implement this requirement at the national level. This may be seen as bringing increased legal certainty and as a clear political sign for the willingness of the international community to achieve the policy objectives of the disclosure requirement. Such a solution, however, is at this stage of the international discussions unlikely to be found any time soon, and will thus take considerable more time to be introduced than an optional solution.

Sanctions for Failure to Disclose or Wrongful Disclosure

In order for the disclosure requirement to achieve its policy objectives, failure to disclose or wrongful disclosure should be subject to legal sanctions. These sanctions should be the same as are imposed with regard to other formal requirements in patent law; accordingly, the sanctions currently foreseen in the PCT and the PLT would apply. In addition, national law could foresee that criminal sanctions such as fines may be imposed, or that judges may order the publication of their rulings.

Conclusions

Based on the preceding analysis, the following conclusions can be drawn:

- Patent applicants should be required to disclose the "source" of "genetic resources" and "traditional knowledge related to genetic resources" in patent applications. This requirement should only apply if patent applicants (or the inventors) do have available information on the source; otherwise, they should be required to declare that the source is unknown to them;
- Due to its policy objective —increasing transparency in the context of access and benefit sharing— the disclosure requirement has to be considered as a formal requirement. Accordingly, the provisions of the PCT and the PLT apply. Furthermore, considering that the international discussions on disclosure requirements in patent law have only just begun, it seems at this point in time preferable to make it optional for States to implement this requirement in their national laws. This way, there is no risk of preempting further international discussions on this issue, without preventing States from taking action at the national level;
- Failure to disclose or wrongful disclosure should be sanctioned according to the current provisions of the PCT and PLT. Additionally, criminal and other sanctions may apply, and
- It has to be considered that patents are generally applied for after several years of research and development activities, and thus considerable time after the initial access to genetic resources and traditional knowledge. Hence, the disclosure requirement does not provide for a remedy with "immediate" effects. Furthermore, the disclosure requirement will only be able to fulfill its policy objectives if in fact patents are applied for. Accordingly, the measure could be circumvented by foregoing patent protection. It is thus self-evident that the introduction of a disclosure requirement in patent law will not solve all the issues arising in the context of access and benefit sharing regarding genetic resources and traditional knowledge. As such, the disclosure requirement needs to be complemented by further measures taken within other legal domains —the majority of them obviously not related to IPRs— in order to fully solve these issues. This notwithstanding, the disclosure requirement presents a viable measure to be taken under patent law which contributes to the resolution of the issues arising.

Proposals by Switzerland to Amend the PCT

At the fourth session of the Working Group on Reform of the PCT of WIPO held in May 2003, Switzerland submitted proposals regarding transparency measures under patent law in the area of genetic resources and traditional knowledge. These proposals contain precise wordings for amendments to the relevant PCT-Regulations. More specifically, Switzerland proposed for the national patent legislation to explicitly require the declaration of the source of genetic resources and traditional knowledge in patent applications, if an invention is directly based on such resources or knowledge. In May and October 2004, Switzerland submitted to WIPO additional comments and further observations, respectively, on these proposals. These proposals are largely congruent with the opinions expressed in this paper.

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The Interface with Existing Intellectual Property Systems: Limits and Opportunities for Existing Intellectual Property Rights

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Purpose

This paper explores the interface between the intellectual property (IP) system and objectives of the Convention on Biological Diversity (CBD) in relation to access and benefit-sharing (ABS). The paper considers relevant aspects of the CBD and the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) with a view to determining what flexibility exists under TRIPS to take national measures in support of ABS objectives, including prior informed consent (PIC), mutually agreed terms and benefit-sharing. Suggestions are also made about the role of IP in an international regime for ABS. The paper focuses on what role IP should have in ABS, rather than debating whether it should have a role at all.

In considering the flexibility provided by TRIPS, and what role IP should play in relation to ABS, particular attention is given to the various proposals in favour of disclosure of origin or source of genetic resources and associated traditional knowledge (TK), and evidence of PIC or benefit-sharing, in applications for patents and plant variety rights (PVRs).

The perspective offered in this paper is one of an IP policy-maker, not a CBD expert, confronted with public interest challenges from the CBD to the IP system. The challenge is not unwelcome, as it provides an opportunity to recall the fundamental rationale for the IP system — public interest — and that IP protection is not an end in itself.

Background

There has been much debate about the role or impact of IP rights (IPRs) in relation to the objectives of the CBD, even before the CBD was concluded. The woolly references to IP, for example, in Article 16 of the CBD, recognizing on one hand that IPRs should be protected in the context of obligations concerning technology transfer, and on the other seeking cooperation to ensure that IPRs are "supportive of and do not run counter to" CBD objectives, provide little clarity about the IP connection and at best reflect a compromise position.

The areas of interface between the CBD and TRIPS, including the impact of the IP system on ABS, technology transfer, protection of TK and the conservation and sustainable use of biological diversity, have been considered in many contexts (including the CBD, WIPO and the TRIPS Council). Much has been written about whether the respective obligations under IP treaties and the CBD are mutually supportive or are in conflict with each other. This paper proceeds on the assumption that there is no actual legal conflict between TRIPS and the CBD, on the basis that it is possible to consistently implement the obligations under both treaties in some way. There is, however, considerable overlap in subject matter, and provisions of TRIPS in relation to patents and PVRs may limit the "possibilities" when it comes to implementation of CBD obligations in respect of ABS (and other areas of interface, not considered in this paper).

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[1] This paper reflects the personal views of the author, not the Ministry of Economic Development.

The IP system has a role, therefore, in relation to ABS and this should be clarified (including in an international regime for ABS) to provide certainty for policy makers and to avoid disputes. Whether this supportive role can be effectively played using the flexibilities available in TRIPS or would require changes to IP standards is a further question and is considered below.

The Role of IP in ABS

In determining the nature of the role of IP in ABS, it is necessary to consider more closely the ABS provisions of the CBD and examine some of the problems that have been identified and the alleged short-comings of the IP system. This section defines the problem to be solved, finds that IP is only incidental to it, but concludes that IP still has a role to play in the monitoring of ABS objectives.

The IP/ABS issues centre on the extent to which the IP system is supportive of or runs counter to the principles contained in the CBD concerning the authority of governments to grant access to genetic resources, subject to PIC and mutually agreed terms, with fair and equitable benefit-sharing (including in relation to TK). A number of commentators have suggested that the IP system thwarts ABS objectives. This is said to occur when patents or PVRs are granted for inventions or plant varieties involving genetic resources or associated TK in situations where PIC has not been obtained and agreement has not been reached concerning benefit-sharing.

In determining whether IP should respond to problems about PIC and benefit-sharing, it is useful to consider the relationship between IP and these concepts. Article 15 of the CBD requires PIC in relation to access, not PIC to the acquisition of IPRs. Article 15 does, however, require that access be on the basis of mutually agreed terms. Whether or not IP rights could be sought and how they could be exploited are conditions that could form part of the mutually agreed terms. In situations where PIC has not been obtained, the connection to IP is at best indirect, as there is likely to have been no agreement regarding IPRs.

In relation to benefit-sharing, IPRs are one possible form of benefit that could be shared, and this could be addressed in national ABS regulations or recorded in an ABS agreement. It should be recalled, however, that in many cases the genetic materials obtained will not lead to a patentable invention or PVR, and that successful commercialization of any claimed inventions is not certain. In the wider scheme of things then, IP may play a fairly small part in the potential benefits that could flow from access.

This analysis suggests that the IP system is not the source of the problem when patents or PVRs are granted (over genetic resources or associated TK) in situations where PIC and benefit-sharing does not occur. The problem is that, in some cases, users of genetic resources do not obtain PIC or negotiate ABS agreements, and may breach conditions of ABS contracts and national laws or regulations. Only in some circumstances does IP form part of mutually agreed terms and benefit-sharing arrangements.

The solution to this problem clearly requires the establishment of systems to facilitate and encourage compliance, and effective enforcement. First and foremost, ABS systems must be established so that processes are available to users of genetic resources to obtain PIC, and these systems do not yet exist in many countries. ABS systems may rely on a range of sanctions for non-compliance including administrative penalties, contract law to enforce ABS agreements, equitable doctrines, tort and criminal provisions.

it is likely, however, that even when these systems and incentives are in place, applications may be made for IPRs in circumstances where national ABS laws or ABS agreements do not allow for this. ABS systems may also have difficulty tracking compliance with PIC and other criteria, especially where ABS arrangements have not been entered into. This is where the IP system can play a supporting role in the monitoring of ABS conditions, even where IP is not a mutually agreed term. So while IP is not technically the problem, it can form part of the solution and assist with monitoring and enforcement efforts.

The IP system can support CBD objectives, including ABS, in two ways: in the application of existing criteria concerning the granting of patents or PVRs (using the flexibilities available under TRIPS), and by the application of expanded disclosure requirements concerning the origin or source of genetic resources and associated TK. These approaches are not necessarily mutually exclusive.

Existing Features of the IP system that can Support ABS: Looking for Flexibility

There are a number of existing features of the patent system prescribed in TRIPS which could be flexibly applied in domestic legislation in a way that may support ABS objectives (including where TK is concerned). These measures would reduce the likelihood that patents will be granted where genetic resources or TK are concerned.[2] Some of the flexibilities listed here relate more to TK than ABS objectives but are considered on the basis that the terms of reference for the elaboration of an international regime on ABS includes TK within its scope. The degree of support to ABS of the "flexibilities" approach is, however, limited to those States that choose to adopt it.

Potential flexibilities in support of ABS (including TK) include:

- Incorporating into domestic patent law all the exclusions to patentability allowed under Article 27 of TRIPS. This could involve excluding plants and animals from patentability (but not micro-organisms), and adopting an expansive interpretation of the exclusions in Article 27.2. This Article enables Members to exclude patentability inventions when it is necessary to protect public order and morality, including the protection of human, animal or plant life and to avoid serious damage to the environment. This might include the prevention of the patenting of inventions based on genetic resources and associated TK where, for example, the commercial exploitation of such an invention is contrary to the values or belief system of indigenous people. This may in effect correlate with failure to provide PIC.
- Application of the criteria for patentability in Article 27.1 —novelty, inventive step and usefulness — to lifeform inventions, in a way that avoids the granting of overly broad patents. This could be achieved by, for example, including as prior art for the purpose of determining novelty or inventive step, any information made available to the public in any form, anywhere in the world. IPR granting authorities could also expand their sources of TK as prior art, provide training to examiners on how to recognise TK and co-operate with IP authorities in other countries to take advantage of expertise concerning TK as prior art.
- Require additional information about the source or origin of genetic resources or associated TK to satisfy existing requirements in Article 29 of TRIPS. This Article requires applicants to "disclose the invention" by providing sufficient information so that a person "skilled in the art" could carry it out. This option is elaborated on in the next section, which considers expanded disclosure proposals.
- Adopting a *sui generis* system for the protection of plant varieties not modelled on the UPOV Convention. Article 27.3(b) of TRIPS requires that members provide for the protection of plant varieties either by patents or an effective *sui generis* system. National plant variety

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[2] There are further examples of flexibility, which may support other CBD objectives (and concerns about the patenting of lifeforms generally), that are not considered in this paper.

laws could require disclosure of origin of the plant materials *used and evidence of PIC of the* country, farmer or TK holder that provided such materials and associated knowledge. Mandatory disclosure may not be consistent with the UPOV Convention, which does not permit requirements other than the standard DUS[3] criteria to be imposed.

Disclosure Proposals

It has been suggested that the IP system could assist with monitoring and possibly enforcement of ABS objectives by requiring the origin or source of genetic resources and associated TK to be disclosed in applications for IPRs. Disclosure of this nature would also serve an IP purpose, by providing additional information that facilitates the determination of prior art. This would lead to better decisions about patentability and would, therefore, enhance the credibility of the IP system. It could also improve the determination of inventorship, and facilitate the working of an invention.

Some proposals go further and require disclosure of the legal context in which the genetic resources or TK was accessed. Some suggest that evidence of PIC and benefit-sharing should be disclosed, in addition to source or origin. Disclosure of this information has no connection to patent principles but could be seen as a supportive measure.

The proposals that are currently being considered by the TRIPS Council and WIPO, and the actual disclosure requirements adopted in countries such as Costa Rica, Brazil, India, Norway and the European Union, contain a number of variants. They may be *voluntary* or *mandatory* (having legal consequences in the case of no compliance), include a *formality* (generally procedural) or *substantive* requirement (having an impact on criteria for patentability), or a combination of these. Formality and substantive requirements can overlap in practice, including in relation to existing disclosure requirements where failure to comply with formalities can in some cases lead to a patent not being granted.[4] Although substantive and formal requirements can have legal consequences, not all consequences will be patent-related in the sense that an application is narrowed or rejected or a patent invalidated or revoked. For example, administrative and criminal penalties may apply where incorrect information is provided.

The proposals that also include disclosure of PIC and evidence of benefit-sharing also vary. In some cases, provision of this information would be in the interests of transparency or good faith, in which case the information would be provided to provider countries or submitted to a centralized repository to assist with ABS compliance. In others, the information disclosed or evidence submitted would have a bearing on whether an IPR was granted. In this case patent granting authorities would be called upon to assess the adequacy of the information provided or might rely on the face value of any certificate of origin provided.

Impacts and Effectiveness

While disclosure may seem like a good idea in theory, there are a number of specific issues that need to be considered to determine how effective it might be to implement in practice, and its impact on IP policy objectives. These include:

- The trigger for disclosure: how direct should the relationship between the genetic resource or associated TK and the claimed invention be? This issue is not clearly addressed in many of the disclosure proposals. The trigger could be closely connected to patent principles, so as to require disclosure where it is necessary to carry out an invention, TK is prior art known to an applicant and relevant to an assessment of novelty, or where a TK holder may be a potential co-inventor. Alternatively, disclosure may be triggered where genetic resources are used in the course of research (being essential or only incidental to it).[5] A key issue is whether derivatives would trigger an obligation to disclose. In deciding the nature of the trigger it would also be necessary to consider difficult questions such as the respective values of naturally-occurring genetic resources, TK and research and development in innovation.

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[3] Distinct, Uniform and Stable (Article 5(1), 1991 UPOV Convention)

[4] For example, failure to provide evidence that the inventor was entitled to access genetic material used to produce the invention could be a formality objection as would failure to pay renewal fees. See also WIPO/GRTKF/IC/5/10, para 31-35.

- ABS systems and competent authorities must first exist for the IP system to be able to support them via disclosure: such systems and authorities do not yet exist in many countries. It is difficult to monitor or collect information about PIC, for example, if systems for obtaining it are not accessible.
- The relationship between national ABS systems in provider countries and IP offices in the country considering an IP application: if disclosure were to go beyond considering information of source as part of assessing existing patent criteria, to evidence of PIC and benefit-sharing being substantive criteria, serious questions would arise concerning the resources and technical expertise of IP examining authorities to make assessments about acts of access, adequacy of PIC and contractual obligations originating under ABS laws in other jurisdictions. Choice of law issues also arise in this context.
- Necessary documentation, such as declarations, copies of contracts or permits, would need to be determined: the establishment of a certification of origin system would address a number of the concerns that have been raised about verification of documentation.
- The impact on innovation of increased regulation and compliance costs: disclosure requirements should be implemented in such a way as to preserve as far as possible the predictability and transparency of the IP system. Concerns about the cost of determining origin or source where it may have its origins in several places would need to be addressed, for example, in the exact nature of the documentation required, and perhaps by only requiring information readily or reasonably available to an applicant.[6] Increased regulation may act as a disincentive to invest in biotechnology, with flow-on effects for the benefits available to be shared with providers of genetic resources and associated TK.

These issues, along with the nature of the obligation to disclose and consequences of the failure to comply, would need to be determined in order to provide certainty to users of the IP system and if disclosure is to be an effective means to support ABS objectives.

Conclusions

The overlapping nature of CBD objectives concerning ABS and genetic resources and associated TK as the subject matter of IPRs under TRIPS suggests a role for the IP system in support of ABS objectives. While a close reading of each agreement does not suggest that a direct conflict exists, in the interests of certainty for ABS policy makers and to avoid disputes concerning implementation, the relationship of IP to ABS should be clarified in the context of an international regime.

While IP is not the major source of the problem when it comes to failure to comply with ABS rules regarding PIC, agreed terms and benefit-sharing, it can form part of the solution, in support of or in addition to ABS systems and other areas of law, including contract, tort and equitable principles. The IP system can assist in two ways: the first is in relation to existing criteria for patentability and the second relates to extended disclosure requirements.

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[5] WIPO/GRTKF/IC/5/10, para 98.

[6] Correa, C.M. , 2003. *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement*, Quaker United Nations Office Occasional Paper 12, August 2003, p 6.

Parties to TRIPS should, therefore, be encouraged to take advantage of the flexibilities available under TRIPS, including in relation to the definition of invention and criteria for and exclusions to patentability, to provide policy space to implement ABS policies. States would be encouraged not to take disputes in relation to flexible interpretations of TRIPS provisions to enable ABS implementation. The moratorium on non-violation disputes under TRIPS should continue to encourage flexible interpretations. Changes to existing standards, for example those related to prior art, might be considered if the flexibilities approach proved unsuccessful.

The IP system could also require mandatory disclosure of the source of genetic resources and associated TK in applications for patents and PVRs, and collect information about whether PIC and benefit-sharing has occurred. Disclosure of the source of genetic resources and associated TK would not be a new substantive requirement for patentability, but it could be used to make assessments about existing substantive patent criteria.[7] An amendment to TRIPS, possibly to Article 29 concerning disclosure, would make it clear that disclosure of this information is permissible and required. Arguably, disclosure of source could be justified as a formality under the present provisions, but not for PIC or benefit-sharing. The legal basis of the disclosure requirement in relation to disclosure of genetic resources and TK would, therefore, be in IP principles, but it could also be connected to ABS law.

The information about whether PIC or benefit-sharing had occurred could be collected, but not assessed, by IPR granting authorities. It could be provided, along with information about source of genetic resources and associated TK in applications, to a competent authority in the provider country (if such authorities are established under an international regime). Alternatively, it might be provided to a central repository managed by WIPO or the CBD that is accessible to providers of genetic resources and associated TK. In this way the IP system would assist with the monitoring of ABS rules in general and ABS agreements where they specifically include IP as an agreed term. The legal basis for disclosure in the case of PIC and benefit-sharing would not be patent principles or IP policy, but be directed towards meeting ABS policy objectives. The IP system would not, however, go as far as to provide sanctions if ABS conditions were not met, as this would stretch the IP system too far beyond its underlying principles, function and purpose.

This paper believes that disclosure of this sort is appropriate and a good idea in theory. It is dependent, however, on ABS systems being established, and a number of practical details (identified above) would be critical to its success. It is also dependent on progress being made on these issues in the TRIPS Council, and such progress has not been rapid to date. There is certainly greater room for appreciation of how IP can serve the public interest in CBD objectives in IP fora.

There is a risk, however, that providing such clarity on the relationship between CBD objectives and provisions in TRIPS may prove redundant given the increasing prevalence of free trade agreements and bilateral and regional agreements concerning IP. These agreements often remove the flexibilities available under TRIPS and impose TRIPS-plus standards. The incidence of these arrangements is, therefore, another issue to take into account in determining the role of IP in an international regime for ABS. This factor does not mean that pursuing clarity on the IP/ABS interface is fruitless, but rather suggests that time is of the essence.

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[7] Correa, C.M. , 2003, p 9-10

Four Reforms for Wider Benefit-sharing

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It is in the interest of advanced countries (which is effectively the United States) that there should be a unitary system of intellectual property rights to cover the whole world. In contrast, all other countries need diversity, because their individual situations are so different. Moreover, the unitary system has developed in ways that simply reinforce the market powers of capability and persuasion, which firms in advanced countries possess in strength. The intellectual property rights which other countries need are therefore rights which will help to compensate for their weakness with regard these other kinds of market power.[1]

Four reforms of intellectual property rights which could contribute to the protection of genetic resources and traditional knowledge as well as to benefit-sharing, are: returning to States the power to limit the absolute monopoly which trade marks deliver; direct protection of innovation; compulsory expert arbitration of disputes; and introducing a financial dimension into the measurement of all grants.

Trademark Reform

In discussions about the effects of intellectual property rights, the enormous economic importance of registered trademarks is almost invariably overlooked. These are much the most valuable of all such rights because they are the basis of *brands* and are not limited in time.

As well as other types of intellectual property rights, TRIPS imposed on poorer countries the requirement to set up a modern trademark regime. A most harmful aspect of this is that it gives the international tobacco firms the laws they need for a marketing onslaught in these countries, to make up for losses in advanced-country markets. As a quite inescapable consequence, smoking-related diseases will increase rapidly in these countries. The resulting harmful effect on vital statistics could even wipe out any victories there may be over, e.g., HIV/AIDS and malaria.

TRIPs prevents anything being done to prevent this because its Article 15.4 (which is a word-for-word copy of Article 7 of the Paris Convention) provides that "The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to the registration of the mark."

Although Article 7 of the Paris Convention prescribes for international registration of marks, there is nothing in it about conditions for their renewal. In the pre-TRIPs era, this meant that whilst an individual Convention member country could not refuse to register a trademark for any category of goods, it was under no obligation to *renew* it. Denmark took advantage of this to put a limit on the term of trademark protection for pharmaceuticals. At the 1958 meeting of the Conventions' members, the International Chamber of Commerce and the Convention Secretariat moved that the scope of Article 7 should be extended to cover renewals, so as to prevent this, but the Danes stood their ground and the proposal was dropped and not revived subsequently. Marketing interests finally got their way in Article 18 of TRIPs, which specifies that trademarks must be renewable indefinitely.

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[1] Kingston, W. , 2004. *Harmonization is a Trojan Horse*, European Intellectual Property Review, 26 (10), pp. 447-460.

This total denial to WTO member States of any control over the most valuable of all the intellectual property rights they grant, is quite perverse in the light of what TRIPs allows in respect of *patents*. Article 27. 2 prescribes that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ... human, animal or plant life or health."

Nothing more than this is needed for trademarks, and TRIPs will simply have to be changed to provide it. In doing this, provision should be included for States to fully control their own trademark laws, so that they can prevent monopolies *in perpetuity* being obtained on products which have originated from their genetic or other natural resources. Moreover, provisions which have the same effect should be incorporated into any new international convention which would include the advanced countries also. Nothing else can lead to proper compensation for the use of these resources.

Direct Protection of Innovation

Originally, intellectual property rights were devised to protect the results of individual creativity. Largely because of the rigidity imposed on the system by the existence of a specific Clause for them in the U.S. Constitution, they have never been adjusted properly to the historical change to *investment* as the source of what needs to be protected.

Consequently, the grant is made to the supposed inventor or author, and the protection the investment receives depends upon how close the link is between them. Copyright works because there is identity (perfection in the link) between an author's text and what is published. There is a close link, amounting to identity, between a chemical invention and its innovation. What is discovered in the laboratory, what is patented, and what is eventually bought and used, are all exactly the same. Protection of the invention consequently protects its innovation very well. In other technologies, however, where the link between invention and innovation is much weaker than it is in the chemical field, a patent for invention gives poor protection for its related innovation.

The solution is to protect innovations directly, not through their link to a supposed creative act of an individual.[2] This is done in the EU Database Directive, which provides for grants to protect the results of investment, with no requirement for originality. It is also used in the outstandingly successful alternative protection to patents for "orphan" drugs provided by the Department of Health in the United States. This is given to the developed and tested drug, ready to go on the market, nor for a mere disclosure, as in the case of a patent. It has resulted in a twelve-fold increase in relevant drugs and both actual and relative declines in death rates.[3]

The type of direct protection of innovation most immediately relevant to the topic under consideration here, is that under the UPOV Convention. In this case, what is protected is not any sort of proposal for or specification of a new plant variety corresponding to a patent disclosure, but the actual innovated plant in a form capable of showing its stability and homogeneity in propagation trials.

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[2] Kingston, W. , 1988. *Direct Protection of Innovation,* Maastricht/Boston, Kluwer Academic.

[3] Lichtenberg, F. R., 2001. *The Effect of New Drugs on Mortality from Rare Disease and HIV*, New York, Columbia University.

Direct protection of innovation consequently appears to be more suitable for innovations originating in traditional knowledge than existing intellectual property rights.

Compulsory Expert Arbitration for Settling Disputes

It is altogether remarkable that so much discussion of intellectual property rights ignores the costs of enforcing them. In fact, these are so great as to swing the balance of advantage completely towards large firms and the advanced countries which are home to the majority of these. In these advanced countries, the amount spent on litigation of disputes has been outstripping that spent on research and development.[4] A U.S. Commission has reported that litigation is quite inappropriate for settling disputes about intellectual property rights and could well remove much of the value of such rights,[5] while an EU Expert Group noted that much of the excessive cost of resolving disputes of this kind is due to the use of the ordinary Courts for dealing with them.[6] These costs make intellectual property rights all but worthless to smaller firms.

It is consequently extremely important that whatever arrangements might be put in place to achieve benefit-sharing, their value will not be destroyed by allowing them to suffer from traditional methods of dispute resolution. Instead, *compulsory* expert arbitration of all disputes should be built into these arrangements from the start. There is persuasive empirical evidence that such an approach has the ability to solve the problem of excessive costs in these kinds of dispute resolution.[7]

Furthermore, any international agreement which does not contain this type of arbitration will be largely worthless. In the most comprehensive research yet done on the fate of European small firms' patents in the United States, for example, it was found that the District Court system in that country was strongly biased in favour of local infringers.[8] This was so evident as to lead to the conclusion that foreign firms should only patent in the U.S. if they have enough resources to appeal from the District Court to the Court of Appeal for the Federal Circuit in Washington, D.C. where (as in the U.S. Patent and Trademark Office itself) they can expect a fair hearing.

Bringing Money into the Measurement of Protection

The proper measure of any economic privilege can only be money. No doubt at the time when intellectual property rights originated, any measure other than time was out of the question, since accounting techniques were undeveloped. To persist with such a poor measure as time on its own today, however, is simply to ignore all the achievements of accountancy since then. This is now capable of providing the measurement required.[9] Many of the problems of intellectual property rights, especially in new fields such as biotechnology and information processing, are actually caused by having to use time as the very crude measure of a patent, copyright or other grant. It can only be by chance that any fixed term will be exactly what is needed to attract the relevant investment, in most cases it will either be too long or too short. There is no reason to think that Lord Kelvin's dictum that "we advance according to the precision of our measures" applies only to science.

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[4] Barton, J. , 1933. *Reforming the Patent System*, 287 Science, p. 1933.

[5] Advisory Commission on Patent Law Reform, 1992, p. 78, United States Government Printing Office.

[6] Strategic Dimensions of Intellectual Property Rights in the Context of Science & Technology Policy: an ETAN Report (1999) Section 3.2.2. Brussels, Publications Office of the Commission of the European Communities, EUR 18914.

[7] Kingston, W. , 2000. *Compulsory Arbitration - Empirical Evidence*, European Intellectual Property Review, pp. 6154-158.

[8] *Enforcing Small Firms' Patent Rights*, Luxembourg, Office for Official Publications of the European Communities, 2001. Accessible at: http://www.cordis.lu/innovation-policy/studies/2001/management03.htm

[9] Kingston, W. , 2002. *Intellectual Property Needs Help from Accounting*, European Intellectual Property Review 24 (11), pp. 508-515.

One way in which a financial dimension could be brought into the measurement of intellectual property rights, which an EU expert Group has recommended for investigation, would focus on the investment which had to be made beforehand to bring about an invention or innovation.[10] It would also introduce compulsory licensing, so that an exclusive right would change from that of "making, using and selling," to that of conditionally allowing others to "make, use and sell."

Some predetermined, socially-acceptable multiple would then be applied to the investment, to define the price of a compulsory license for access to it. Payment of this price would allow a late-comer to use an originator's information by sharing retrospectively in the investment , weighted by the risk which had brought the information into being.

Multiple licenses

It would be essential that the more precise means of measurement did nothing to reduce the incentive to undertake the high risk of investment in invention and innovation. A safeguard for this is that the more important any information is seen to be by competitors, the more licenses will be requested for it, and as each license would earn the same amount, the originator could find that his risky investment was very well rewarded. This reward might be greater than could have been achieved under traditional protection, because several trajectories of incremental development would then be exploited simultaneously, which is also the best possible way of expanding the total market for the originator's benefit. At the same time, any other firm could join in developing a new market as long as it was ready to share retrospectively in both the investment and the risk which the originator took to make that market possible.

It should be stressed that the multiple licenses would only set the price at which the originator of information would *have* to grant a license for its use by another. The proposed arrangements would not prevent any type or number of license agreements between willing buyers and willing sellers. Any license which would be granted under the present system, therefore, would equally be available under the new one.

Introducing a financial dimension to the measurement of patent grants would also ensure that firms could not hi-jack the results of research carried out with public funds, as can happen at present. This is because the multiples which they could charge for a license on any downstream invention of their own would only apply to the amount of R&D investment they themselves had made. The same would apply to investments to make use of genetic resources, traditional knowledge or folklore, and multiples could be adjusted to deliver any desired type or level of benefit-sharing.

Feasibility of measurement

To examine how "multiples" might be calculated in practice, the records of 23,000 cases from United States Small Business Innovation Research Programs (SBIR) were examined.[11] What makes these records so valuable for this purpose is that an SBIR award covers all research costs, including the firm's normal overhead.

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[10] *Strategic Dimensions of Intellectual Property Rights in the Context of Science & Technology Policy*, Note 6 above, Section 3.4.

[11] Kingston, W. , 1994. *Compulsory Licensing with Capital Payments as an Alternative to Monopoly Grants for Intellectual Property, Research Policy* 23 (5), November, 1994, pp. 1275-89.

The results from them show that at the time when a protected new product has just gone on the market, and a license to compete with it is sought by a second firm, a payment of 2.2 times the originating firm's investment in research and development to date would put both parties on an equal footing. Information has been generated through investment at different levels of risk by the originator, and his competitor, who has neither invested nor taken any risk, now wants to use it too. Payment for a license at a multiple of 2.2 represents the second firm's retrospective sharing of the first firm's investment, along with its risk.

Similarly, at an earlier stage, where enough information had been produced to obtain a patent or to make a prototype, and the second firm wished to obtain a license to use this, the SBIR figures suggest a multiple of about 4 (which of course would be applied to a much smaller amount because it is earlier in the investment process) to make both parties equal. In practice, multiples should be higher than these to give weight to the unmeasurable factor that is the courage of the originator in actually making the first investment. Multiples should encourage action, not "wait and see."

Comparison with known returns to pharmaceutical R&D offers a further insight into how the multiples could work. This shows that if three licenses on an invention were bought at a multiple of no more than 2, the returns from it would match those of the most profitable "blockbuster" drugs. Two licenses would give the originating firm very significant profits, and even a single one would enable it to cover the costs of its R&D investment.

The convergence of these results from using a multiple of 2 on pharmaceutical inventions with the figure of 2.2 obtained empirically from the SBIR data is encouraging. It suggests that this more precise measurement of intellectual property rights is quite feasible. Its advantages make it worth considering for any new *sui generis* protection arrangements proposed for benefit sharing in relation to generic resources and traditional knowledge.

Post Script

Having listened to several presentations at the Workshop about Certification for benefit-sharing, I cannot avoid the conclusion that these are attacking the problem from the wrong end. I explain by analogy:

It is well known that lottery winners often have trouble handling their very large prizes. Imagine, therefore, that a benevolent national government, or a group of such governments, decided to help by providing a counseling service to deal with this harm. They could offer this either to winners or to anyone who buys a ticket, but clearly the latter procedure would be highly wasteful of resources, since only the tiny minority of winners could actually benefit from it.

Any form of Certification would be just like giving counseling to every buyer of a lottery ticket, and just as wasteful, since the odds against their being relevant are of the same order of magnitude in both cases. Clearly, therefore, just as the focus in the counseling case would have to be on the trivial number of winners, so in that of the CBD it must be on the very limited number of products which contain some genetic material. With modern techniques, this material can now be traced back to its origin, whose owners, it is accepted, are entitled to share some of the value of the products to which it has contributed.

How could this be achieved? There seemed to be an underlying assumption in the discussion, going back to the Convention, that this should be by agreement between the parties on the basis of PIC, and furthermore that such agreement would be mandated by whatever is finally negotiated internationally. Agreement, however, could only be a practical arrangement if it comes about before a product starts to be developed, because at any time afterwards the developer could be held to ransom by the owner of the material. Even then, it would be very wasteful, because it would require large numbers of trans-national negotiations about the sharing of potential rewards which in all but a trivial number of cases will never be realized in practice.

The logic points instead towards allowing products to be developed and marketed freely, and then imposing a small "source levy" on their sales. This could be collected by national governments and paid over to an international Benefit-sharing Secretariat for distribution to the owners of the original genetic material, or of TK, through these owners' own national governments.

It seems to be unrealistic to think that the requirement of prior informed consent could be provided by any smaller entity than the national government of the source country, whether the subject matter is genetic material or traditional knowledge. Furthermore, it should be possible for this consent to be counted upon by potential users. Ruth Okediji's contribution to the Workshop discussed the difference between a property rule and a liability rule in relation to information. In the former, there is no access without the permission of the owner, but in the latter access is free, with whoever takes advantage having to pay compensation for doing so. Clearly, in the biodiversity resources and benefit-sharing cases, it is the liability rule which should be used. One drawback which it has is that it can lead to wasteful litigation about the amount of compensation to be paid. For this reason, measurement by money rather than time, and compulsory arbitration by technical experts, should be built in to the intellectual property rights component of any international agreement, for the reasons advanced in my Workshop paper.

I was told that in earlier negotiations industry representatives balked at any suggestion of imposing a tax. To make the "levy" approach more acceptable to industry, two conditions are required: firstly, that the rate should be low and secondly that it should only apply once a product has reached some minimum level of turnover. Since it would be applied to sales, it would allow benefit-sharing throughout the product's lifetime, and would not be limited to any period of patent protection. A levy on sales can be very low indeed and yet provide very substantial funds over the long term, because trade mark protection for such sales has no time limit. I stressed in my presentation why those responsible for drafting CBD protocols should pay particular attention to trade marks under the TRIPs regime.

As to the use of the intellectual property system in general, I also discussed how in its present form this is inappropriate for preserving biodiversity and achieving benefit-sharing. It is not likely to be repaired in the near future. However, a change, not in the law which shapes this system, but in the procedural rules of Patent Offices, could be useful, and might be achievable within the time-scale needed for the CBD.

This change would apply to the requirement, in the United States Patent Office for example, that an applicant for a patent must call the Examiner's attention to all prior art of which he is aware. Failure to do this carries the powerful sanction that any patent granted as a result could be invalid. It would be an easy matter for this requirement to be extended both to any knowledge of relevant genetic material or from traditional sources, irrespective of whether or not this could be considered to be prior art.

Any significant acceptance of a scheme along the above lines by developed countries would contribute towards redeeming the great loss of trust in them by others, which is the legacy of the way in which the WTO, and, above all, TRIPs, were brought into being. Also, since the only countries which could receive levy funds would be those which subscribed to the international arrangements as suggested, this would be an incentive for them to join in these, which seems to be lacking at present.

The point made by Susan Finston in her Workshop paper that the pharmaceutical firms have been moving away from developing new products based upon genetic materials or traditional knowledge in favour of synthesizing products from resources they already have, deserves closer attention. This trend seems to owe as much to unrealistic expectations on the part of people in developing countries and their advocates in developed ones, as it does to inappropriate procedures for obtaining access. Since the entire population of the world losses from this, solving the problems of access and benefit-sharing is worth a great deal of effort.

Access, Benefit-sharing and the Interface with Existing IP Systems: Limits and Opportunities

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It is fairly well-established that the intellectual property baseline for protecting innovative/creative endeavor poses important challenges for considerations of an appropriate legal framework for the protection of biodiversity, genetic information and associated traditional knowledge. Of those challenges, the non-economic values often associated with the protection of animal and plant life, the timeless character of traditional principles that underpin conceptions of ownership, and an entirely different perspective on what constitutes "property" or "knowledge" stand out as significant limitations of existing global proprietary schemes. Notwithstanding these concerns, the principles attendant to cultural systems that generate and support the development of traditional knowledge are, to varying degrees, already captured by aspects of the orthodox intellectual property (IP) system.[1] Consequently, the interface between existing categories of intellectual property rights and a *sui generis* legal framework for the protection of traditional knowledge and biodiversity merit ongoing attention to determine how the IP system might affect a new international regime. The relationship between IP and access and benefit-sharing is particularly crucial given the weakening criterion for IP protection in developed countries, which has resulted in an even more significant overlap between traditional knowledge, biodiversity and IP subject matter. Such shifting legal standards in developed countries will have an important impact on the security and stability of new legal forms designed to govern access and benefit-sharing arrangements (ABS).

The following brief comments will focus on strategic ways the IP system might influence the formulation of normative principles as well as the design of a legal framework for an international ABS regime.

First Principles: the Appropriate Regulatory Design

Discussions about the insufficiency of the intellectual property system as a strong or preferable model for traditional knowledge focuses on a number of challenges that include the problem of valuing traditional knowledge, both for purposes of developing substantive norms to govern protection as well as to facilitate how ABS might be implemented. It is important to note, first, that the design of a regulatory framework is not necessarily connected to the mechanisms or principles used to appropriate economic gain to the owner. For example, patent or copyright protection in and of themselves do not guarantee economic gain for the innovator or creator. Economic value is more likely the function of market forces but it is undoubtedly the property right that facilitates the appropriation of such economic gain. With this in mind, let us then consider the problem of how to set values for traditional knowledge.

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[1] See the matrix depicting possible correlation between intellectual property subject matter and traditional knowledge.

The Problem of Value

Two principal goals are generally associated with proposals for ABS. The first is the prevention of misappropriation and/or misuse of traditional knowledge (including plant and animal life). A second goal is to manage access to and protection of biodiversity by ensuring that any economic value derived from traditional knowledge is extended to the rightful owners of that contribution. The first issue raised by these two goals involves the conceptualization of "value." As many commentators have pointed out, traditional knowledge encompasses immeasurable components —religious, cultural, and moral— that make the task of legal definition and protection under the intellectual property system less than meaningful for most traditional knowledge owners and providers. While the intellectual property system, with its categorizations and formal requirements, is in tension with the value systems reflected by traditional communities, both systems to some extent share the public goods characteristics of non-rivalrous consumption and non-excludability. In other words, multiple individuals can use the knowledge without depletion of the original, and once produced there is no way to prevent others from enjoying its benefits. Consequently, legal rules that govern ownership are necessary to preserve the ability of owners to set a value on the goods at issue.

It is the case, however, that the valuation of intellectual property rights is typically divorced from the substantive principles that govern protection. In other words, the value of patents, copyrights, trademarks or tradesecrets is not reflected in the norms of protection *per se*. Instead, these categorizations of intellectual property reflect the type of creativity at issue and to some extent, the presumed level of investment. Likewise, how we define "traditional knowledge" is not as much the issue as making sure a rule exists that governs the terms of access to this knowledge. The fact is that the IP system also recognizes forms of non-economic value. The system thus structures ownership rules that allow owners to control access and use by others. In the IP context, value is typically accounted for in the nature and extent of remedies available for misappropriation. For example, in copyright law the concept of wilful infringement draws on non-economic standards of ethical/ moral conduct. Wilful infringement thus attracts significantly higher penalties. Furthermore, the availability of statutory damages[2] in copyright suggest that economically "harmless" infringement is still compensable and would be meaningful to the owner whose non-economic interests in, or connection to, the work may have been adversely impacted by the infringer. Thus, even in the absence of explicit recognition or protection for non-economic harm, the notion of value as reflected indirectly through the availability of certain types of damages is cognizable under the traditional intellectual property system.

Another insight for traditional knowledge protection can be found in the flexible definition of valuable information under tradesecret law. Like copyright law, and to a more limited extent, patent law, tradesecret law in leading developing countries observes considerable discretion in compensating violations of intellectual property rights in a manner that reflects both the value added positively by the creators' knowledge and the value reflected by knowing negative information that is, information about what does *not* provide a remedy to a particular problem. This form of "negative" knowledge or information is valued in tradesecret law as a "blind alley,"[3] that is, information that gives an individual a positive gain by saving costs associated with investigations that are unlikely to succeed. Thus even if traditional knowledge does not result in a positive economic value in terms of a patentable product, any lead time gained by learning from traditional knowledge would still be compensable under the tradesecret regime. In addition, since tradesecrets are protected as part of a larger regulatory system for addressing personal harm, the kind of emotional, cultural or spiritual concerns inherent in traditional knowledge systems could benefit from protection under this scheme.

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[2] These are damages that the copyright owner is entitled to without a showing of any actual economic harm caused by the infringer. *See* 17 U.S.C., 504(c).

[3] See Restatement (Third) of Unfair Competition, § 39, and Uniform Trade Secrets Act, §1(4) which define trade secrets as any information that can be used in business or other enterprise, and that is not generally known. Under some proposals, a misappropriation model could also sanction unauthorized or otherwise illicit use or diversion of information whether or not such information is held in secret. See, e.g., J.H. Reichman, Legal Hybrids Between the Patent and Copyright Paradigms, 94 Colum. L. Rev. 2432 (1994). The misappropriation model (regardless of the secrecy status) has been considered for genetic information in publicly sold agricultural products. See Note, The Genetic Message from the Cornfields of Iowa: Expanding the Law of Trade Secrets, 38 Drake. L. Rev. 631 (1989).

For traditional knowledge that is associated with art, ritual, and performances, there is also the strong possibility that the concept of moral rights might add a positive layer of protection to traditional knowledge. A new ABS regime could eschew the categorizations of IP subject-matter but still employ doctrines that would promote stability, consistency and coherency in the interface between IP and ABS subject-matter. In sum, concerns about the incompatibility of intellectual property and traditional knowledge that revolve around "value" should be reconsidered in light of the recognition and protection of non-economic values that already exist within the intellectual property system.

The Strategy of Overlapping Rights

Despite the ostensibly rigid categorization of intellectual property, there is considerable overlap between copyright, patents and trademarks or tradesecrets. A single product may be subject to multiple, and overlapping rights. For example, a pharmaceutical drug may be subject to patent protection for the actual drug; there may be protection for the process; the package design is subject to copyright protection while the name of the drug is protected by trademark law. Each layer of protection addresses distinct creative or innovative elements, and allows the owner to continue *de facto* legal control of certain markets when one set of rights may have expired.

In considering various regulatory schemes for traditional knowledge protection, it is important to emphasize that rigid categorization or definition of what is being protected (is it more like patent or copyright? More like copyright or trademark?) is increasingly less relevant in the intellectual property system. New technologies, market convergence (or segmentation) and malleable legal standards that constitute the normative core of each category of protection have resulted in an intellectual property scheme that is more like a continuum rather than a classification system. Traditional knowledge should benefit immensely from this system of overlap, particularly given the rational reluctance to make traditional knowledge "fit" into precise subject matter categories.

This same benefit flowing from minimal distinctions between subject matters can also be a limitation in considering the design of ABS regulation. The increasingly weak standards of patentability in developed countries, are precisely what makes traditional knowledge even more susceptible to misappropriation. Low standards of originality, inventiveness and utility, especially in the biotechnology area, more likely heighten interest in genetic information and other raw materials. The possibility of patenting some forms of traditional knowledge may compel a legal framework that can straddle both a sui generis system of protection at the national level, and the international intellectual property system. Hence, identifying ways to constructively navigate between both systems will be an important aspect of designing a successful ABS regime.

Coordinating between ABS Models and the IP System

Extra-IP Models of Protection: Tension and Contradiction

Property rights in and of themselves are usually insufficient to protect the full range of an owner's interest. Regardless of the form of property, owners will at various points require protection from other legal sources to supplement their interests. In some cases, such alternative regimes may completely replace property rights. For example, an innovator may choose to protect his/her patentable product or process by relying on the tort of misappropriation to prevent unauthorized access to and use of the item at issue. Such an approach may be strengthened by relying on contract law to bind consumers who purchase the product to utilize it only on the terms set by the owner.

Much of the appeal of a *sui generis* protection system for traditional knowledge lies precisely in the open-endedness of a loosely regulated system. Torts, contracts or other quasi-property rules are not subject to duration rules that are associated with intellectual property rights. *Sui generis* systems can avoid the limitations of twenty years for a patent term, or life plus seventy years for copyright, to more fully account for the timeless values that undergird traditional knowledge. Interestingly enough, resorting to extra-intellectual property regimes in developed countries has occurred primarily as a means to *circumvent* some of the access mechanisms embedded in the structure of the intellectual property system. Thus, for example, legal protection for works not subject to copyright protection has been secured through contract law. This result, which can undermine the public interest values embedded in the copyright scheme, ironically has strong prospects for ABS by granting greater control to owners in setting terms of access and use of genetic material, plants and other aspects of traditional knowledge that would not benefit from intellectual property rights. Contractual protection, not intellectual property, thus potentially offers the greatest level of protection (control) for ABS. Whether such a strong level of control is consistent with the CBD, or even TRIPs is contestable.[4] There is also the significant problem of extra-territorial enforcement of contracts that govern ABS arrangements. The possibility of simultaneous protection under an IP system would make extra-territorial enforcement of ABS schemes more feasible under the foreign country's IP system, particularly where the breaching party is located in a developed country with strong domestic IP enforcement.

Transacting Over Traditional Knowledge: Liability Rules versus Property Rules

The possibility of a regime outside of the intellectual property system for ABS raises the fundamental question of appropriate legal baselines. A property rule is a legal entitlement that permits infringement (use) only after negotiating with the owner. Property rules permeate the intellectual property system and have been the dominant choice for international intellectual property treaties. On the other hand, a liability rule regime allows use to occur through an implicit license, and the appropriate compensation is determined subsequently. Of course, variations on the distinction between a liability rule and a property rule can be designed and, in features of both regimes even co-exist.[5]

In the context of ABS, the possibility of a liability regime has been seriously tendered as an alternative baseline for traditional knowledge and other forms of creativity[6] deemed to be incompatible with the traditional justifications for intellectual property protection. Features of the dominant proposals for ABS revolve around a property rule approach typical of existing sui generis regimes in other areas. However, a liability rule system offers some important solutions for chronic concerns about the high transaction costs associated with ABS systems. These transaction costs result from the dispersed nature of traditional knowledge and associated biodiversity, the possibility of multiple groups that own (use) the same knowledge in different geographical areas, and the problem of assigning ownership to knowledge that is communally generated. The tremendous challenges these issues bring to the traditional intellectual property table, have forced most commentators and scholars to advocate a *sui generis* system to address these issues. In the intellectual property system, high transaction costs have caused industry participants to invest in institutions that facilitate the efficient exchange of intellectual property rights. In a liability rule regime, such institutions are unnecessary because the system permits automatic use. However, there still remains the question of assessing, enforcing and collecting the costs of accessing ABS. For this reason, there will still be a need to give serious attention to the development of institutions necessary to effectuate the objectives of any ABS model.

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[4] Both the CBD and TRIPs require a balancing between a number of objectives. Art 8(j) of the former requires countries to balance environmental protection, ABS and respect for traditional knowledge. TRIPs requires a balance, among other things, between incentives to create, access for public interest goals and economic development. A regime that gives concentrated control to owners without the opportunity to consider other public concerns, may be ill-advised at this stage.

[5] For example, although copyright is designed around a property rule, certain musical works are subject to a compulsory licensing scheme akin to a liability rule.

[6] See, e.g., Reichman, J.H., 2000. *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743. (favoring liability rules for innovation that fails legal standards for protection under patent or copyright regimes).

An Opt-in, Opt-out Possibility

The availability of alternative legal sources for the protection of creative endeavor creates an "opt-in" system, where creators choose the kind of protection model that is suitable for their interests. In many instances creators choose tradesecret protection, contract based protection, or a collection of other legal theories to protect their rights and interests. In essence, even where IP protection is available for a particular product, creators can choose a different protection method. For example, some empirical studies suggest that small and medium size firms often eschew the expensive patent system and opt, instead, for tradesecret protection or other forms of protection based on unfair competition laws. While the public benefit flowing from these alternatives is significantly less than what the IP system in theory offers,[7] these alternatives are also less expensive and raise fewer transaction cost problems in the market.

Like intellectual property systems, negotiations over an international ABS regime should contemplate the possibility of allowing "owners"[8] to choose the intellectual property framework for protection where possible, to remain exclusively within the ABS framework or, to straddle both. Appropriate mechanisms for coordination between the two would, of course, be necessary and borrowing from the IP system in ways that I sketched out earlier is one way of coordinating between both regimes. At the very least, IP mechanisms or doctrines can be used to supplement the ABS system which could be particularly useful in an international setting where these different regimes must co-exist.

Finally, note that owners of creative products often rely on a multiplicity of doctrines to secure market power. A well-crafted overlap between ABS and IP rights will enhance the goals of both systems and limit tensions that might undermine a nascent ABS regime.

Conclusion

The weakening of patentability standards, and other legal requirements for intellectual property rights, suggests that the interface between intellectual property and ABS is likely to be appreciable for the forseeable future. Indeed, it is likely that any ABS system created is likely to be a hybrid of IP rights, contracts and unfair competition. Whatever the combination of normative principles in any emergent ABS regime, it seems clear that the IP/ABS interface must be navigated in a way that facilitates coordination, transparency and accountability in the international context, without abandoning the public interest in access, benefit-sharing and innovation.

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[7] Commentators often point to the fact that the public benefit that comes from the disclosure (and dissemination) of inventions is lost when firms choose alternative avenues for protection.

[8] In an ABS context, the determination of "ownership" is probably best left to national laws. In the IP context, ownership issues are also typically determined by national laws

Interface: A Possible Matrix

Major IP Categories	Subject Matter	International Legal Standards	TK/ABS	Major International Regime
Patents	Ideas, processes, plants, designs, genetic sequences	New, useful, non-obvious	Processes, know-how, systems, chemical compound	Paris Conv., TRIPS, UPOV IUPGR
Copyrights (including neighboring rights)	Creative Expression (art, music, literature, dance)	original work of authorship; perceptible	music, dance, crafts, designs, folklore	Berne Conv., TRIPS, WCT, WPPT
Trademarks	distinctive symbols, signs, insignia, words, letters, short phrases	capable of distinguishing goods	geographic names, cultural identifiers, tribal marks	Paris Conv.,
Tradesecrets	unknown information that has value	secret, has commercial value, reasonably maintained as a secret	Sacred processes, formulas, know-how; identification of plants and plant properties	TRIPS, Madrid TRIPS, IUPGR

DISCUSSION PAPER
Pharmaceutical Industry Scenarios and Questions Relating to Patent Disclosure

European Federation of Pharmaceutical Industry Associations (EFPIA)

Scenario 1

1. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains the seeds (with appropriate consent) and grows sufficient quantities to enable it to extract and purify the oils which it then sells. It patents the purified oils, their use and the process of extraction and purification. Would the disclosure requirement apply?
2. Company A is informed that rubbing a bruise with a leaf from the XYZ tree in Brazil alleviates bruising. It obtains quantities of the leaves (with appropriate consent) and isolates and synthesises the active ingredient which it develops and then sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
3. Company A obtains (with appropriate consent) leafs from 100 species of trees in Brazil. It knows nothing about their properties. Using various assay techniques, it discovers that one ingredient of one of the leaves is medically useful. It isolates and synthesises the active ingredient which it develops and sells. It patents the active ingredient and its use. Would the disclosure requirement apply?
4. Under 3, does it make a difference to the applicability of any disclosure obligation if the medical use was known to a community in Brazil but not disclosed to Company A either at the time of collection or before application for the patent?
5. Company A does either 2 or 3 but finds that the ingredient it has isolated and synthesised has unacceptable toxicity. It finds a hitherto unknown analogue of it in the same class of compounds and patents and commercialises that analogue. Would the disclosure requirement apply?
6. Company A does 2, 3 or 5 but does not commercialize the product. On the basis of the patent disclosures of Company A, Company B develops, patents and commercializes a compound in a different class of compounds from those patented by Company A. Is there a need for Company B to disclose the origin of the leaf used by Company A? Does it make a difference if Company A had disclosed its origin?

Scenario 2

One of the thousands of compounds synthesised by Company A as part of its combinatorial chemistry program is Compound X. Its screening processes disclose that this novel compound has a medical use. It patents the compound and its use. However, Company A cannot develop a cost-effective method of producing commercially-viable quantities of the compound and does not commercialize it.

Company B is aware of the patent disclosure. It obtains access to a large number of micro-organisms from Brazil and discovers (it is not told) that one of them naturally produces Compound X, but not on a commercially efficient scale or with adequate purity.

Based on this discovery, it analyses a similar micro-organism which is native to Europe and finds that that micro-organism produces Compound X more efficiently than either the micro-organism from Brazil or the synthetic route disclosed in Company A's patent.

Company B genetically modifies the European micro-organism to improve production efficiency still further. It patents the micro-organism and compound X as produced by the micro-organism.

Company C genetically modifies the European micro-organism still further to improve the purity of Compound X and obtains relevant patents.

Companies A,B and C cross-licence each other under the patents to enable sale of the commercial products.

Does Company A, B or C have to disclose the Brazilian micro-organism?

Scenario 3

1. Company D is informed that people wash clothes with a plant extract from Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme. It isolates the gene for the enzyme and patents the isolated enzyme, its DNA sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
2. Company D is informed that people wash clothes with a plant extract in Chile. It obtains the plant (with appropriate consent) and discovers a new lipase enzyme, isolates its gene, and determines its DNA sequence. The company finds, however, it cannot withstand normal laundry temperatures, and publishes the work. Company E reads the publication and undergoes extensive R&D to mutate the gene to make the gene more heat stable. The new gene shares only 40% sequence identity with the original gene. Company E patents the mutated enzyme, its gene sequence, its use in laundry detergents and a process for its recombinant production. Would the disclosure requirement apply?
3. Under 2, does it make a difference to the applicability of any disclosure obligation if (i) Company D worked with Company E to generate the new enzyme and a joint patent application was filed? (ii) Company E later exclusively licenses Company D to make and sell the enzyme in washing powder? (iii) Company D did not publish, but gave Company E the information under a contractual obligation to pay royalties to Company D should a commercially viable enzyme be marketed.
4. Under 2 or 3, does it make a difference to the applicability of any disclosure obligation if Company D never discloses to Company E the source of the plant, and the plant is also found to be native to the country of Company D and Company E.

Scenario 4

1. Company F is informed that a plant virus is wiping out a cash crop native to Bolivia. The company obtains the plant (with appropriate consent) and discovers a receptor which the virus uses to infect the plant. The DNA sequence of the receptor is found and the receptor is cloned and used to screen compound libraries for chemical antagonists which would prevent viral infection. A patent application is filed on: the new receptor, its gene sequence, methods

of finding antagonists, the chemical antagonists themselves, and their use. Would the disclosure requirement apply?

2. Under 1, does it make a difference to the applicability of any disclosure obligation if the receptor was found by the Bolivian Agricultural Department, and its sequence published, and i) Company F was given the vector comprising the gene for the receptor by the Bolivian Agricultural Department and the antagonists were found and patented?, or ii) Company F synthesised the published gene sequence to discover and patent the antagonists?

Scenario 5

Consider all of the above cases and assume that, for whatever reason, relevant patents are held invalid. Producers of generic/unpatented products make large amounts of money selling the products. Are those producers obliged to share the benefits of their sales with the countries which provided the materials?

Scenario 6

In order to make a wheat crop more hardy, plant breeders crossed a conventional wheat variety with a variety obtained from Russia (with appropriate consent). Plant Breeders Rights were obtained (under UPOV) for the new variety. Would the disclosure requirement apply? What if several breeding steps were required to generate the new plant variety, and the Russian variety had been used 20 steps previously to the new variety being generated?

DISCUSSION PAPER

Biodiversity-based Patent Term Extension: An Opportunity for Using the Existing IP System to Support ABS

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There is a need for an open discussion of the potential role of existing IP rights in achieving the Convention on Biological Diversity's objectives — conservation, sustainable use and equitable benefit-sharing. The following discussion is limited to patent terms.

In a knowledge-based economy, innovation processes take on many of the characteristics of the production processes of the industrial economy. From this perspective, the innovation value chain consists of various inputs — raw materials, information/science/knowledge, informatics, capital, labour — which are employed in the development and marketing of an innovative commercial product or process.

The biodiversity-based innovation value chain may consist of; inter alia, biological resources, genetic material, traditional knowledge, taxonomic/genomic/proteomic information, basic and applied science, proprietary R&D, regulatory approval research, IP protection and marketing expenditures.

In general, the existing intellectual property system provides protection in support of investments in inputs in the latter stages of the biodiversity-based value chain such as patents/plant variety rights/ trade secrets, regulatory data protection and trademarks/trade dress. Currently, however, there is little IP protection at national or international levels afforded upstream inputs in the value chain.

Under the Convention on Biological Diversity (CBD), Parties agreed to principles for recognizing the sovereign rights of Parties over their genetic resources and principles governing access to and use of the traditional knowledge of indigenous and local communities. Several countries have begun to implement Article 15 (Access to Genetic Resources) and Article 8(j) (Traditional Knowledge) under national law. These laws are in effect new forms of *sui generis* property rights.

The international ABS regime will necessarily entail both higher costs for use of some inputs in the value chain —genetic resources and traditional resources— and new regulatory and transactions costs associated with obtaining prior informed consent and negotiating mutually-agreed terms. Scientists and industry can view ABS in two ways. In the short term, ABS policy will increase input and regulatory costs. In the long term, ABS policy will help conserve a critical input for sectors using biotechnology.

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[1] The views expressed are solely those of the author.

The pharmaceutical industry context for negotiating an international ABS regime is that the high cost of clinical trials to prove safety and efficacy is inflating drug costs and there are growing pressures from many governments to control health care costs (including drug prices). The high cost of drug regulatory approval is dominating the cost structure of the pharmaceutical industry and in the end will greatly affect the ability of the drug industry to allocate additional rents to other inputs including genetic resources. Outsourcing of clinical R&D to developing countries should provide some cost relief in the coming years and if this is the case the future cost structure may afford more opportunity for providing compensation for accessing and using genetic resources.

From a CBD perspective, ABS instruments leading to a higher valuation of genetic resources are desirable if benefit-sharing leads to *in situ* conservation and sustainable use of biodiversity. A shared goal is to minimize the regulatory burden of any ABS regime but realistically there will be some new administrative and enforcement costs associated with this regulatory and property rights regime. Perhaps the nature and level of administrative and enforcement costs of intellectual property rights are useful for comparison's sake when designing an ABS regulatory system.

There are some additional economic challenges facing ABS policy-makers that patent term extensions may have a potential role in addressing:

- Firstly, biodiversity-based innovation must compete with other drug discovery pathways such as combinatorial chemistry and human genomics. An ABS regime that increases the cost of genetic resources risks providing a disincentive for biodiversity-based research and as a result existing biodiversity based investment may shift to other innovation pathways. Patent term extensions have been used to compensate for investments in the public interest; for example, US patent term extensions to encourage pediatric clinical research. Patent term extensions can be justified for biodiversity-based research to support society's environmental and health goals since the preservation of species is in effect protecting our future "medicine cabinet". Patent term extensions for biodiversity-based research would lead to a shift away from other innovation pathways towards ABS-related investments, thereby creating economic incentives for governments and stakeholders to reduce the rate of loss of species. The financial cost to society of biodiversity-based patent term extensions would be deferred for 20 years when the patent extension term begins.
- Secondly, the biotechnology and pharmaceutical sectors are competing (albeit poorly) for biological resources against resource sectors (e.g. forestry products). Conserving species and ecosystems is essential for ensuring that genetic resources will be available for biotechnology and pharmaceutical research by future generations. Currently, the value of timber per hectare far exceeds the current market value of genetic resources per hectare. When it comes to preserving genetic resources, market conditions and incentives and resource management practices are highly skewed in favour of the resource sector over the biotechnology and pharmaceutical sectors. While there are strong long-term interests for the biotechnology and pharmaceutical sectors to actively support the conservation of genetic resources, to date these sectors have not actively engaged in the public policy debate. Unless there are new innovative market incentives and/or significant government conservation measures many of the world's species will be lost during the next 50 years. Biodiversity-based patent term extensions may be part of the solution. Patent incentives that support foreign direct investments in biodiversity-based research should also provide an incentive for governments to take additional measures to conserve biodiversity.

My support for biodiversity-based patent term extensions is qualified. User country measures, new *sui generis* rights or other measures, which will help ensure benefit-sharing from the use of genetic resources and traditional knowledge, will be necessary to ensure that additional rents resulting from patent term extensions are appropriately distributed to upstream inputs in the biodiversity-based innovation value chain.

DISCUSSION PAPER

Intellectual Property Issues: A revision of the current UPOV PVP is required to support the conservation, sustainable development and benefit sharing goals of the CBD

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The issue of IPRs has mostly, if not completely, been reviewed in the context of the CBD solely in regard to how IPRs can assist in monitoring compliance. However, it is critical that the role of IPRs be looked at in a more holistic sense. Do available forms of IPR help support the goals of the CBD in regard to conservation, sustainable development and benefit-sharing? If they do not then there are more fundamental issues that need to be addressed than the more narrowly defined legal issues currently occupying centre-stage of the debate. To answer this question it is essential to review IPRs in the biological context of evaluating and utilizing plant genetic resources. Scrutiny by legal experts may lead to an excellent formulation for interacting IPRs with the CBD. All legal efforts will be for naught, however, unless the biological aspects of using plant genetic resources are also considered and taken into account. After all, the CBD is a convention that applies to *biological* diversity.

The most widely used type of legislated IPR that is used globally to encourage research and product development by plant breeders is Plant Variety Protection (PVP), under the UPOV scheme. PVP has a breeder exemption that allows immediate free access to commercialized varieties for the purposes of continuing the breeding process (provided the variety is not subject to other forms of IP). PVP and the breeder exemption make sense in the context where well-adapted varieties provide the building blocks from which even better adapted varieties can be created. PVP does not, however, provide sufficient incentives for a breeder to take extra time, to apply additional resources, and to take risks that are inherent to evaluate, adapt, and introduce new genetic diversity into a region from an exotic source. Even in the previous pre-CBD era, where plant genetic resources were considered the "common heritage of humankind", there was little to no use of exotic germplasm by the private commercial sector. The introduction of exotic germplasm into a region was largely conducted by the public sector (including national programs, public universities and International Agricultural Research Centres). However, public investments in agricultural research have not kept pace with the acknowledged needs. In developed countries, the annual growth rate of real public investment in all agricultural research fell from 2.7% during 1971-1981 to 1.7% for 1981-1991. Similarly, in developing countries, the growth rate of public investment in agricultural research fell from 6.4% in the 1970s to 3.9% in the late 1980s. Of greater concern, variety development has been a decreasing percentage of all agricultural research. Real funding for the International Agricultural Research Centres has increased, but by less than 1% per year between 1985 and 1996 (Pardey et al., 1997). On the other hand, private sector investment in agricultural research has generally increased, tempered by the IPP available.

Capabilities of the private sector to contribute to genetic diversity on farms is ultimately dependent upon the extent to which breeders can effectively source and deploy exotic germplasm. Sourcing and deploying exotic germplasm are longer-term and more high-risk activities than is breeding from already well-established and well-adapted high yielding varieties. Consequently, intellectual property regimes that encourage the high-risk activities that are required to source and deploy exotic germplasm have a key role to play in encouraging more genetic diversity in production agriculture. In contrast, current PVP regimes that allow immediate and free access by competitors to newly developed varieties undermine willingness of any one breeding program to undertake high-risk activities required to source new, initially unadapted germplasm and they will therefore lead different breeding programs to be using ever more similar germplasm pools. The private commercial sector could be an important contributor to helping achieve the goals of sustainable development and the generation and sharing of benefits foreseen by the CBD. Current PVP regimes, however, not only fail to encourage private investments into the additional time consuming and high-risk activities that are essential to find and to deploy exotic germplasm, but their confluence with new technologies and breeding approaches also conspire to provide perverse incentives that, if left unchanged, will lead private commercially funded plant breeders not to consider exploring new exotic plant genetic resources.

For example, new technologies include:

- high-throughput semi-automated molecular marker profiling;
- off-season winter nurseries giving multiple generations per year;
- high-throughput gene expression assays using DNA on silicon chips;
- high-throughput proteomics assays;
- high-throughput DNA sequencing facilities;
- ability to DNA profile both the female and male parents of hybrids without accessing either parent per se via use of maternally inherited tissue (e.g. use of pericarp tissue);
- ability to create homozygous progeny very rapidly using di-haploid genetic stocks;
- ability to conduct genome-wide gene-trait association studies involving hundred or thousands of genotypes including landraces; and
- ability to conduct genome-wide scans comparing domesticated varieties or landraces and to compare with wild relatives to identify potentially useful loci and potentially useful new genetic diversity.

The endeavour of plant breeding exhibits "path-dependence". Progress along a new path (e.g. using exotic germplasm) places initial costs and risks on the breeder, though all entities eventually benefit. The issue of access to exotic germplasm therefore becomes of paramount importance. One potential application of the technologies listed above is to reduce the time taken to breed a new inbred line from a commercial hybrid by about 10 years; from 12 years down to 2 years. The level of incentives for the private sector to engage in research to identify and to introduce new exotic germplasm from one region and to introduce it into an improved adapted variety in another region of the world has therefore further diminished to the point of essential non-existence (in an environment where competitors have free immediate access to that new variety). Commercially funded plant breeding organizations cannot afford to make long-term high risk investments to introduce new genetic resources into a region, if those varieties are then immediately available to competitors in their breeding programs. Yet, it is critical that incentives are in place to introduce new genetic resources into a region to add new useful diversity, to counter the narrowing of the genetic pool that occurs when adapted varieties of that region are the sole genetic base, and to contribute to benefit-sharing that can accrue to providers of exotic genetic resources (as envisioned as a key basis of the CBD).

The current forms of UPOV allow immediate and free access by other breeders to commercial varieties for further breeding. Consequently, investment incentives by the private sector to conduct innovative and high-risk research and development of new and improved germplasm will decline under the current UPOV system, if that form of protection is the only IP available to the breeder. Allowing free and immediate access to commercial varieties actually provides perverse incentives for breeders not to invest in high-risk innovative research and product development because the results of their research and product development are immediately placed in the public domain for others, including those breeders who make no investments in such risky or innovative breeding strategies. Consequently, under the research environment provided for by the current UPOV scheme, economic incentives encourage breeders to make relatively low risk investments in product development by utilizing already adapted starting materials. As such, in the current UPOV environment, commercially funded plant breeders have no incentives to utilize exotic germplasm. No demand for exotic germplasm means there can be no market for the use of those resources, no benefits to potential providers of those resources, and no benefits that could otherwise accrue to consumers. Current forms of UPOV style protection do not support the goals of the CBD. PVP as it is currently practised undermines the capacity of the private sector to access exotic germplasm.

Nonetheless, the general concept of a PVP-type system is appropriate and still has importance to provide affordable IP for plant breeders whilst retaining the availability of germplasm as an initial source of variation in breeding. However, it is time to update the provisions of UPOV to accommodate advances in technology that have occurred since 1991, in order to encourage continued infusions of new germplasm into breeding pools, and also to help support the goals of the CBD. Updates to UPOV might include a new option for a PVP with a revision of the breeders' exemption. This revision might include a period of "x" years from the date of a PVP application during which the breeders' exemption would not be available for UPOV-protected material including commercialized varieties or it could provide for licensed use in breeding. Perhaps such a revised UPOV could be available at a higher fee to applicants, thereby supporting genetic resource conservation (e.g. via the FAO International Treaty and/or the FAO Global Plan of Action) and also including additional benefit provisions to providers of genetic resources via bilateral PIC arrangements. Perhaps a revised PVP scheme could co-exist with current forms of PVP as an additional option or plant breeders to consider using.

A revised UPOV would contribute to an improved solution. IPP, as applied to plant breeding, must be improved on a global basis to attract research investments and to encourage use of a broader base of genetic resources. There are numerous dependencies upon crop germplasm that cut across country and continental boundaries. Therefore, increasing incentives to invest in breeding on a global basis are required to encourage both access and benefits. More effective IP can encourage access to germplasm and can ensure benefits flow to providers of germplasm. Changes in UPOV are required on a worldwide basis to achieve the twin goals of increased, more sustainable and reliable food production and improved environmental quality. A revised UPOV system could facilitate achievement of the goals of the IT and CBD by providing increased opportunities for benefit sharing to germplasm providers through increased incentives to holders of germplasm to conserve and to evaluate those resources and increased incentives to commercially funded plant breeders to access and to provide benefits from the use of those resources. If a new UPOV system is not made available, one that supports commercial breeding using exotic germplasm, then the private commercial sector will be seriously hampered in its ability to contribute to the generation of benefits and the sharing of those benefits that are envisioned in the CBD.

DISCUSSION PAPER

IPRs and the International Regime on Access to Genetic Resources and Benefit-sharing.

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International action to protect genetic resources, access to such resources, and the benefits obtained from their use, must take into account that most countries already have in place distinct treaties and agreements related to commerce, IPRs and genetic resources, but that the vast majority of these still lack a specific national law on Access to Genetic Resources and Benefit-Sharing (ABS).

As such, it would be reasonable to assume that countries with different IPRs, international treaties and regimes will face serious problems if they want to achieve the goals of the Convention on Biological Diversity (CBD) and may not be part of (or at least comply with) an international legally-binding ABS regime.

In light of this, it is important for all CBD contracted Parties to understand, and be fully aware of, all the relevant intellectual property treaties and agreements, in order to meet the general provisions of any mandatory, legally-binding regime. This should be independent of their international IPR obligations and compromises, and take into consideration special and differential treatments for countries depending on their development and their own national legislation.

To comply with such an objective, it is necessary to first consider that many different countries are members of different treaties and agreements that have a considerable impact on the intellectual property protection of genetics resources and associated benefit-sharing. For example, it is important to consider the following: 148 countries comply with the TRIPS agreement, 181 comply with the WIPO treaties, 124 countries are signatories to the Patent Cooperation Treaty (PCT), 59 are part of the Budapest Treaty on the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedure, 57 are members of the International Union for the Protection of New Varieties of Plants (UPOV), and 22 are part of the Lisbon Agreement (for the Protection of the Appellations of Origin).

In issues related to biological diversity, we must consider the following facts: there are 188 Parties to the CBD (although only 168 are signatures; the CBD has not been ratified, for example, by the United States of America), 109 Parties make up the Cartagena protocol of Biosafety (103 signatures), the FAO has 188 members, although only 55 countries have ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (Mexico is not a ratified country).

From this data, it is clear that any International Regime on Access to Genetic Resources and Benefit-

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[1] The views expressed are solely those of the author.

Sharing (IR-ABS) will depend on the knowledge of both National and International bodies and agreements, and that it is not possible to achieve the goals of the CBD if negotiations are solely linked or biased towards a specific treaty, agreement or organization. A very significant fact is that a considerable number of countries are not part of the most important legally-binding IPR treaties and agreements (i.e. PCT and UPOV) which will have to be modified in order to comply with the CBD and, in particular, with the concerns of Article 8(j).

In conclusion, any proposal for an International Regime must consider the differences in the international obligations of those countries that are Party to the CBD. A initial approach to help solve this problem could be based around an attempt to get missing CBD members to sign or ratify specific IPRs agreements or treaties (for example PCT and UPOV), and to get the Conference of the Parties to invite the different Organizations to negotiate or consider, within their specific contexts, all the assets necessary to achieve an effective International legally-binding Regime on access and benefit-sharing.

B:Limits to rights over Genetic Resources. The Issue or Derivatives: Defining the fine between and Intangible Property Rights.

Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives.

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The International Regime on Access and Benefit-sharing (IR-ABS)

On the whole, the negotiation of an International Regime on Access and Benefit-Sharing (IR-ABS) offers the opportunity to agree upon a multilateral frame of rules and procedures to promote and to safeguard the fair and equitable distribution of benefits arising out of the utilization of genetic resources and its derivatives, as well as of the knowledge, innovations and practices of indigenous and local communities for the conservation and sustainable use of genetic resources and derivatives.

These rules and their mechanism of compliance and enforcement would have to be complemented by legislative, administrative or policy measures among developed country Parties, a system of incentives for both providers and users, a mechanism of transference of technologies and know-how to developing country Parties, a financial mechanism, and other means that would facilitate the operation of the regime including a process of communication, education and public awareness.

Property Rights, Genetic Resources and Derivatives

A clear distinction of rights and obligations of Contracting Parties that are *developing countries of origin of genetic resources and derivatives* from those other Parties that have acquired these resources in accordance with the Convention on Biological Diversity (CBD), is a critical condition for a successful IR-ABS.

For this distinction, profound implications arise at all levels, in particular concerning the rights, obligations, and expectations of local communities, authorities, suppliers, investigators and users of both genetic resources and their derivatives (GRD).

Rights and Obligations of the Nation-State in Countries of Origin

Recent policy research in Colombia[2] has come to the conclusion that the rights of the country of origin of the GRD can be better understood by means of the following two concepts:

- The general interest as an attribute of the sovereign rights of States over their natural resources, and
- The genetic resources and derivatives as public patrimony of the Nation.

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[1] The views presented in the above text are those of the author and do not reflect the position of the government of Colombia in the negotiations on the International Regime on ABS.

[2] These notes are based in extracts of the project: "Policy of Access and Use of Genetic Resources in Colombia" proposed by the Alexander von Humboldt Institute.

Accordingly, the authority of national governments to determine access to genetic resources, subject to national legislation, gives these authorities administrative property over GRD as well as the public role of creating conditions for their access, conservation and sustainable use.

Due to the States' responsibility as administrator of inalienable resources, national governments exercise the role of safekeeping and monitoring GRD as well as being held accountable for guaranteeing national sovereignty over these resources, along with the rights of the indigenous and local communities and associated traditional knowledge.

Rights and Obligations of the Providers in Countries of Origin

The government of the country of origin exerts rights as provider when that country is the direct supplier of the GRD. This situation arises from GRD that are located in public lands or lands that have been declared as protected areas, including *in situ* conservation efforts as well as *ex situ* collections under the State's administration. In all other cases, the supplier will be a third party. In such an event, it is necessary to define the rights and obligations under national laws of those who provide GRD, including local communities, research institutions, and *ex situ* collectors.

In Bolivia, Colombia, Ecuador, Peru and Venezuela, all members of the Andean Community, GRD are inalienable resources, that is to say, these resources are public property. Therefore, according to this legislation, genetic resources and their derivatives can neither be sold, nor bought. There are no private property rights over the tangible and intangible components of GRD.

Bearing in mind the Andean Community Law on access to genetic resources and derivatives[3], all suppliers of GRD should have the following rights recognized:

- Rights of possession of the GRD, when there is complete evidence that the provider has been conserving the intrinsic value of biological diversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of these resources;
- Rights of Prior Informed Consent (PIC) on the utilization of genetic resources and its derivatives in the case that the providers have been recognized a right of possession, and
- Rights to the benefits arising from the utilization of genetic resources and its derivatives in the case that the providers have been recognized a right of possession.

In all the above cases, the obligations of the supplier are to be supportive of, and not to be counter-productive to, GRD of a national interest and/or public patrimony of the nation. Furthermore, providers should not contravene any of the stipulations of Andean Decision 391.

Rights and Obligations of Providers/Users from Parties that have Acquired GRD in Accordance with the CBD

According to numerous research papers and other references,[4] providers are converted into users when applicants wanting to access GRD have been granted legal authorization by national authorities from the country of origin. This is to say that providers from Parties that have acquired GRD in accordance with the CBD, fall in the category of applicants for the effects of national ABS regulation.

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[3] Decision 391 of 1996 regulates access to genetic resources and derivatives, and Decision 486 of 2000 regulates industrial property.

[4] A number of these research and policy papers are cited or referred to at: www.biodiv.org

This type of 'second floor' provider includes *ex situ* gene banks, located inside and outside the country of origin, or any other collector or researcher that has previously obtained access to GRD from an *in situ* supplier in a country of origin.

The applicant for authorization to use GRD acquires, by means of a contract with the country of origin, a set of rights and obligations that do not include ownership over these resources or their inherent information.

On the side of the country of origin, national authorities should recognize that the applicant/user/provider from a country different from the country of origin is given the following rights:

- The right to use GRD under conditions and obligations mutually decided upon by the national authority and the applicant. This use does not cover the transference or acquisition of the property of these resources, because they are public property and therefore non-transferable. The applicant will neither be able to transfer the property of such resources to a third party. In addition, the user cannot change the agreed end-use of GRD without the permission of the authorities of the country of origen;
- The right to claim immaterial property[5] on the developments that are obtained from the use of the GRD and the value which the developer or inventor adds to such resources (subject to intellectual property rights). This can include knowledge or information on resources, including new products or processes technologies, methodologies or services, and
- The right to be informed by the national authorities from the country of origin —in a clear, transparent and opportune way— about the conditions and terms in which access to GRD will take place.

According to the Andean Community[6], however, the competent national authority may, either *ex officio* or at the request of a party, and at any time, declare a patent null and void, if:

- The products or processes related to the patent which is being filed have been obtained and developed on the basis of genetic resources or their derivatives originating in one of the Member Countries, and if the applicant failed to submit a copy of the contract for access to that genetic material, and
- The products or processes whose protection is being requested have been obtained or developed using traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, and if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries.

On the user country's side, "each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights".[7]

For transparency and accountability reasons, the legal authorization to use GRD, that is, a copy of the contract for access (if the products or processes for which any patent application are being filed were obtained or developed from genetic resources or derivatives of countries of origin), should be placed in the CBD Clearing-House Mechanism.

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[5] Here we are referring to patents and other intellectual property rights that allow a "down stream" user a monopolistic right for a limited amount of time on immaterial products of intellectual nature and of creative content, by virtue of, the exercise of the holder of the right.

[6] Decision 486, 2000, Article 75.

[7] CBD, Article 18.

If applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous and local communities should be available as well in the CHM.

Property Rights on Tangibles and Intangibles

Material or immaterial property?

Addressing the issue of the tangible component of GRD involves recognition that *in situ* genetic resources and their derivatives refer to any living thing, either complete or partial, as found in nature, which means all natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing.[8]

One of the problems that hinder the question of bioproperty, and indeed the false distinction between tangible and intangible features of genes and molecules, is the absence of an adequate definition of genetic programs and their intrinsic relationship to genes, proteins, cell types, and other features of biological organisms including any plant, animal or microorganism containing functional units of heredity.

As stated above, the Andean Community considers GRD as inalienable, that is, they are public part of the patrimony of the developing country of origen. Access granted for specific uses of GRD do not include the property of these resources or their inherent genetic information (genetic programs).

In practice, concerns regarding the distinction between tangible genetic resources and intangible genetic programs have already been expressed within different international agreements such as The FAO International Treaty on Genetic Resources for Food and Agriculture, The Bonn Guidelines and the Andean Legislation. In all of these instruments, there is language that prohibits, or at least questions, the reclamation of intellectual property rights on genetic materials and genetic programs found in nature.[9]

Intangible or immaterial property

Immaterial property over knowledge and innovations is well accepted within Member Countries of the TRIPS Agreement and the Andean Community.[10] Within these agreements, patents are granted for inventions, whether goods or processes, and all areas of technology that are new, involve an inventive step, or are commercially applicable.

International rule-making institutions such as the World Trade Organization (WTO) set a range of obligations that protect intellectual property related to the knowledge, techniques and technologies that modify, transform and add value to the GRD.

Nevertheless, without adequate infrastructure, know-how and training, developing countries of origin are not protected from technology investors that do not contribute "to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[11]

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[8] Decision 486, 2000, Article 15.

[9] Annex B of the Bonn Guidelines of 2002; Article 12 of the International Treaty of Genetic Resources for Food and Agriculture (2002); Andean Decision 486 of 2000.

[10] Decision 486, Article 14.

Actually, the mere protection of ideas[12] is not as important as recognizing that both access to and transfer of biotechnology from developed to developing countries (which are the providers of GRD) are essential elements for the attainment of the objectives of the CBD.[13]

Limitations on access[14]

The Andean Community may establish, through an express legal ruling, partial or total limitations on access to GRD in the following cases:

- Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;
- Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access-related activities;
- Adverse effects of access-related activities on human health or on elements essential to the cultural identity of nations;
- Undesirable or not easily controlled environmental effects of access related activities on the ecosystems;
- Risk of genetic erosion caused by access related activities;
- Regulations on biosafety, or
- GRD or geographic areas rated as strategic.

Collective property over ancestral genetic resources and derivatives

Because of the fundamental role of GRD with added ancestral (cultural) value, the Andean countries recognize the historic contribution to biological diversity made by indigenous and local communities, through its conservation and development, the sustainable use of its components, and the benefits generated by such use.

The recognition of traditional values and uses implies an attempt to exclude from Andean legislation the exchange of genetic resources, derivatives and associated traditional knowledge for their own personal use, based on their own customary practices.

Furthermore, in the case of domesticated or transformed genetic resources and derivatives, the rights over these resources, when traditional knowledge is involved, are seen to belong to indigenous and local communities, including the selection or improvement of GRD by traditional techniques, and those that have been conserved, used and developed in a time and specific cultural space.

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[11] TRIPS Agreement, Article 7.

[12] It would be worth the trouble to consider the arguments of the economists Michele Boldrin and David Levine when they propose that the society does not have to recognize property rights on ideas and would only have to do it in the case of physical or tangible objects. To see: Boldrin, Michele, and David Levine. 2003. "The CASE against Intellectual Monopoly" Californian University of Los Angeles, draft book manuscript. First two chapters download from http://www.dklevine.com/

[13] CBD, Article 16.1 and 16.3

[14] Decision 391, Article 45.

Scientific research

If GRD have an added value as a product or process of scientific research, the intangible or immaterial property of theses results belong to the inventor or innovator. When this value is added in the country of origin, it should not be appropriated by users from other countries. The competent national authority may declare a patent null and void, if intellectual property rights over innovations generated in the country of origin are claimed, since information related to GRD should be part of any prior art examination.

The Issue of Derivatives

The CBD has recognized biotechnology as any technological application that uses biological systems, living organisms, or derivatives there of, to make or modify products or processes for a given specific use.[15] Clearly, markets and institutions worldwide consider the biotechnological use of genetic resources of actual and potential value for a number of economic sectors —particularly agriculture— and for novel bioindustrial products such as biopharmaceuticals, nutriceuticals, cosmeceuticals, dermaceuticals, and bioinformatics.

According to the CBD definition, biological resources includes genetic resources. In addition, the Andean Community recognizes the actual and potential value of using a genetic resource or its derivatives. In this context, the Andean countries define derivatives as "a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings".[16]

In fact, access to derivatives is the most frequent form of genetic resource use. The importance of their inclusion within the scope of the IR-ABS arises from the fact that countries of origin exercise sovereign rights over their derivatives. Access granted for specific uses of derivatives, therefore, does not include the property of these derivatives or their inherent biochemical information. Moreover, if derivatives are excluded from an IR-ABS, most of the potential value and benefits of adding value to derivatives will be monopolized by large corporations from developed countries.

As result of ignoring derivatives in the IR-ABS, indigenous and local communities will become the real losers, since in developing countries of origin an important part of traditional knowledge is related to derivatives.

Opportunistic users of genetic resources could ruin the construction of networks of reciprocal confidence, benefit-sharing, and thus frustrate efforts of long-term cooperation among Parties. In addition to the negative effect of ignoring derivatives, intellectual property rights inappropriately focused on private rents and the exclusion of competitors, may result in monopolies on value-added derivatives that would impede technological innovation and the transfer and dissemination of biotechnology.

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[15] CBD, Article 2.

[16] Decision 391, Article 1.

DISCUSSION PAPER

A Plant Chemist's Perspective on the "Problem" of Derivatives

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This paper offers some practical considerations from a laboratory scientist's perspective on challenges of trying to regulate plant based "derivatives" under ABS policies. If one were to generalize about the character of medicinal plant chemistry professors at universities (acknowledging the inherent danger of generalizations), they could be considered a somewhat eccentric lot, driven by a passion to understand the chemical mysteries of plants. Medicinal plant chemists tend to be more collaborative than competitive. Not surprisingly, within the "culture" of plant chemists, an extensive system of barter has quietly evolved around plant collections, extracts and derived compounds. It is this culture of collaborative exchange that adds a layer of complexity to any ABS regime that seeks to label, track, or otherwise regulate the flow of derivatives between different individuals, laboratories, institutions and countries.

From the perspective of a medicinal plant chemist, plants are miniature chemical production factories. Plants convert simple inorganic substances (carbon, hydrogen, oxygen, nitrogen) into all sorts of complex and scientifically interesting chemical compounds, many of which are useful to humans. The job of the plant chemist is to take the plant apart, separating it into its chemical constituents (i.e., derivatives) and testing these for various medicinal properties and biological activities (e.g., anti-viral, anti-inflammatory, anti-cancer, etc.). Depending on the plant species, the specific types of chemicals being studied, and the laboratory equipment available, this kind of laboratory work can take weeks, months or even years.

Some plant chemicals are ubiquitous, found in many different species; others are novel to certain species of plant and some are only produced at certain stages of growth or under certain environmental conditions. Some plant chemicals, once identified, can be synthetically created in the laboratory; others are too technically difficult, time-consuming or expensive to synthesize and will need to be extracted from the plant. Some chemicals that fall into the latter category can be partially synthesized in the laboratory (semi-synthetic) or their biosynthetic machinery can be cloned into a simple plant or bacterial system that can be grown in high yield in the laboratory and induced under artificial conditions to produce the chemical.

Since the biological diversity of plants is so great (over 250,000 species on earth) and the chemical repertoire of each plant species is so vast (i.e., hundreds or thousands of chemicals per plant), most medicinal plant chemistry labs specialize in certain species of plants and/or families of chemicals, and limit testing to certain categories of medicinal properties. Regardless of a lab's specialty, the most labor intensive and time-consuming part of the scientific process is generally the field collection of plants and the initial extraction of plant compounds (usually conducted by students as part of their undergraduate training or graduate research projects).

In the context of medicinal plant research, the life of a "derivative" is one of promiscuity. For example, Lab X has a collection of 600 plant extracts from location XX that it is testing for anti-viral properties. Meanwhile, Lab Y has 400 extracts from location YY that it is testing for immune-stimulating activity. The labs agree to test one others' extracts as an exchange of favours, perhaps leading to a collaboration in future if there are any results of interest. The savings in time and cost to each lab are obvious —essentially neither could do what the other lab is already set up to do. So new scientific knowledge that would not otherwise be possible is gained by the exchange. The labs exchange their samples by simply sealing small amounts of each extract in plastic vials, putting them into a nondescript envelop, and sending them off (locally or internationally) in the mail. If the package doesn't reach its destination because it is opened by postal workers or customs officials (an uncommon occurrence in this author's experience), it is usually easy to just send another package. Or a student who is making the journey for other reasons might put the samples in a pocket or suitcase and deliver them in person.

Medicinal plant laboratories are often approached by herbal, biotechnology or pharmaceutical companies looking to conduct quality control tests on the company's products, or to purchase plant extracts for testing in their company's laboratory assay systems (the graduate students having already put in the "sweat capital" into collecting the plants and creating extracts). Natural products chemistry is chronically under-funded by academic granting councils, so university researchers commonly turn to these kinds of opportunities to supplement funds for purchasing laboratory equipment and materials. Again, the derivatives quietly move between labs, institutions and sometimes countries.

Can these flows of materials, whether given, traded or sold, be tracked and regulated by an ABS regime? Perhaps, but it will take the cooperation of many individual scientists to make it happen —individuals who are not likely to be amenable to any system that they view as overly bureaucratic and burdensome to the point of interfering with conducting their science. In other words, if ABS requirements are seen as too onerous, the exchanges will simply go "underground". Thus, systems for the labeling and tracking of derivatives need to be designed with the practical realities of the "derivers" (generators and users of derivatives) in mind; these groups likely have limited time, resources and expertise to put labour intensive or technologically sophisticated systems in place.

Derivatives are a form of scientific currency that facilitates scientific discovery through a system of collaboration and reciprocal exchange. In the spirit of protecting and assigning rights to genetic resources and derivatives, an ABS regime should not inhibit scientific collaboration and discovery. Getting the users of genetic resources and generators of derivatives involved in designing systems that meet policy needs and at the same time are feasible in practical terms will be key to any effective ABS regime.

DISCUSSION PAPER

Derivatives

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Introduction

The issue of derivatives generates considerable debate and confusion. This paper addresses the two issues involved and suggests a way forward.

What does the CBD say?

Article 2 of the Convention provides the following definitions:

- "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity;
- "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity, and
- "Genetic resources" means genetic material of actual or potential value.

Article 15 applies those terms as follows:

- 15.1 Recognizing the sovereign rights of States over their natural resources, the authority to determine access to *genetic resources* rests with the national governments and is subject to national legislation;
- 15. 2 Each Contracting Party shall endeavour to create conditions to facilitate access to *genetic resources* for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention;
- 15. 3 For the purpose of this Convention, the *genetic resources* being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the *genetic resources* in accordance with this Convention;
- 15.4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article;

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[1] The views expressed in this paper are those of the author and do not necessarily present those of the Australian Department of the Environment and Heritage.

- 15.5. Access to *genetic resources* shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party;
- 15.6. Each Contracting Party shall endeavour to develop and carry out scientific research based on *genetic resources* provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties, and
- 15.7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms. (my underlining)

What is the Problem?

Discussants are using the term "derivatives" in two different ways and this can generate responses that do not address the underlying concerns raised with the result that heat, rather than light, is generated by the discussion. So how is the term being used or understood? I suggest that the use of the term for one group of discussants reflects their underlying concern that it is necessary to legislatively control the responsibilities of parties during their commercializing or utilizing of genetic resources they have obtained in order to secure the fair and equitable sharing in benefits arising from such developments. Accordingly in this instance, the word 'derivatives' is used in the sense of new products or innovations that come from the source material.

The second use of the terms reflects a different concern. This is that the language of Article 15 is self-defeating. In their view, measures that simply deal with 'genetic resources' are intrinsically inadequate and do not allow nations to benefit from the intent of Article 15. They see the intent of Article 15 as thwarted by the fact that the value of genetic resources lies in their components, in the interaction of genes and in the biochemicals they express (eg proteomics). These essential components of genes and gene function are what these discussants refer to when they talk of "derivatives".

Resolving the Problem

The first concern is already addressed by the CBD through the Bonn Guidelines. When implemented, national legal frameworks establish the mechanism whereby *as a condition of being granted access* the user of genetic resources is obliged to enter into a benefit-sharing agreement. That agreement in turn determines how benefits flowing from that use and *including benefits from any innovation or product developed or otherwise derived* from the genetic resources are to be shared with the provider of access.[2]

Thus, as has been pointed out in earlier debates at CBD COP 6 and later CBD meetings, the issue of the management of benefits from derivatives is resolved through benefit-sharing agreements.

I now turn to the second area of concern: the perceived limitation of the existing definition of "genetic resources". The concern is that the power to regulate access to "genetic resources" is not adequate, as it does not allow for access to the things contained in and with the genes. This is what is referred to in the second usage of the term "derivatives". Can the existing definition of genetic material include these derivatives? I suggest that the answer is yes. As can be seen from the above definitions, "Genetic resources" means 'genetic material of actual or potential value'. This means that we have to have regard to what 'Genetic material' in turn means. The CBD defines "Genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity."

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[2] See the Bonn guidelines at page 14, paragraph 44 (i)

So what does "containing functional units of heredity" mean? Firstly its scope is wide: "*any material* of plant, animal, microbial or other origin" (my underlining). Secondly it refers to "containing functional units of heredity". This latter term is undefined. However, if we take our understanding of that term from contemporary science then we would have to understand it as referring to all the elements that are necessary to establish *functional* units of heredity. This then includes genes (including their constituent elements) and the factors that control their expression and their direct products including RNA and protein. Our understanding of functionality is steadily expanding and it is clear that a functional unit of heredity is the sum of a number of interacting physical factors not simply a piece of DNA.

If this understanding is acceptable then the second "derivatives problem" is resolved. If not, countries can still exercise the general authority over the disposition of their natural resources as set out in Article 3 of the CBD. Alternatively they can ensure that any benefit-sharing agreement, whether required under national laws for access to genetic resources under article 15 or more broadly under Article 3, contains clauses dealing with the material in question.

C:New Forms of *Sui Generis*

Sui Generis Protection of Genetic Resources and Associated Traditional Knowledge

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At the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD), the Parties adopted decisions on ABS and Article 8(j) which can be interpreted as supporting the development of *sui generis* regimes under the CBD.

COP7 Decision 19 mandated the Working Group on ABS, in collaboration with the Working Group on Article 8(j), to elaborate and negotiate an international regime on ABS "with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention."

COP7 Decision 16 is of interest to this discussion in that it requests the WG8(j) "to explore... the potential of, and conditions under which, the use of existing as well as new forms of intellectual property rights can contribute to achieving the objectives of Article 8(j) and related provisions of the Convention."

COP7 Decision 16 on Article 8(j) and related provisions includes an activity to develop elements of *sui generis* systems for the protection of traditional knowledge, innovations and practices which would recognize elements of customary law relevant to the conservation and sustainable use of biological diversity, traditional knowledge and biological resources.

This paper will consider the issue of *sui generis* protection of genetic resources and associated traditional knowledge from the three perspectives reflected in the above paragraphs:

- *Sui generis* protection of genetic resources and associated traditional knowledge under national access and benefit-sharing laws;
- *Sui generis* intellectual property protection of genetic resources and traditional knowledge, and
- *Sui generis* protection of genetic resources and traditional knowledge which is outside the scope of IP rights.

National ABS Laws

National-Level Access to Genetic Resources

Under national ABS laws, new forms of *sui generis* protection of genetic resources and traditional knowledge are evolving. My view is that national access laws can be comprised of two distinct and separate *sui generis* regimes. Under the CBD, States have sovereign rights over their own biological/genetic resources and the implementation of Article 15 (Access to Genetic Resources) at the national level is in effect creating new *national-level sui generis* property rights based on the principles of prior informed consent and mutually-agreed terms. Many countries enacting national ABS laws broadened the scope of this to include traditional knowledge associated with genetic resources and this expansion was reflected in both the scope of the Bonn Guidelines and the COP7 decision to negotiate an international regime. The second *sui generis* regime that is evolving under national ABS laws is one of community-level *sui generis* rights based on indigenous and local community prior informed consent and benefit-sharing for traditional knowledge and related genetic resources accessed and used for scientific and commercial purposes.

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[*] The views expressed are solely those of the author.

It is still not clear as to whether the *sui generis* rights over genetic resources created under national ABS laws will ultimately manifest themselves as real property, intangible/information property or intellectual property. Biological resources are unique when compared to other resources (inanimate matter) used to develop innovative products and processes.

The enforcement challenges cited by countries with national ABS laws illustrate that what we are dealing with straddles real and intangible property. Enforcement of access at the in-situ level resembles resource management policy where harvested resources are generally treated as real property. The economics and nature of the enforcement of genetic resources and derivatives in the marketplace more closely resemble that of intellectual property rights. While the prior informed consent procedures under national access laws may regulate access to genetic resources primarily as real property (e.g. granting permission for physical access to the biological resource), in the process of negotiating mutually-agreed terms contract clauses are defining new intangible property rights related to the potential commercial value of the genetic material/information contained in the biological resources.

The certificate issue also seems to be getting at the nature of these real property/*sui generis* property rights issues. Prior informed consent certificates could accompany biological material (as real property) being exported/imported but a certificate system in the marketplace applied to derivatives and products of genetic resources in some way extends rights beyond concepts of real property.

Community-level Access to Traditional Knowledge and Associated Genetic Resources

Issues related to the second type of *sui generis* regime currently being evolved will be discussed more fully under the panel on community-level prior informed consent for accessing traditional knowledge and genetic resources. However, it is worth considering how *sui generis* protection may be applied to both traditional knowledge and genetic resources.

Community-held Traditional Knowledge

Sui generis protection of community-held traditional knowledge can borrow elements from the traditional protocols governing access to and use of traditional knowledge by indigenous and local communities, as well as some aspects of trade secrecy law. In Canada, indigenous communities are negotiating protocols with resource companies which govern access procedures and the use of traditional knowledge. These protocols are being developed with significant community input and it is through this inclusive process that community interests related to traditional protocols are being respected.

It is illegal for a company to pay a competitor's employee for access to industrial secrets. The same principle of fairness provided to trade secrets under national law ought also to apply to secret traditional knowledge. It has been common practice, however, for scientists and companies to access community-held traditional knowledge through an individual community member.

Trade secrecy rights also come with certain obligations. For example, in order to get redress under the law from unauthorized access to confidential information, companies are obligated to take certain measures to reasonably protect their trade secrets from others. Under a *sui generis* regime to protect secret traditional knowledge, indigenous and local communities would likely be expected to take appropriate measures (e.g. the use of traditional protocols governing individuals of the community) to protect traditional knowledge from unauthorized access. Communities would also need to develop prior informed consent (PIC) procedures and make these publicly available so that the access process is transparent. Flexibility is needed at the community-level since prior informed consent procedures will vary from one community to the next. A *sui generis* regime for accessing traditional knowledge based on this model would consist of the published PIC procedures at the community level coupled with a national level legal framework which supports the legal status of community level PIC regimes.

Community-level Access to Genetic Resources

The issue of community-level access to genetic resources is an issue that has not been considered at CBD meetings in any detail. Where land claims have been settled in Canada then indigenous peoples have unique opportunities through their law-making powers to regulate access and benefit-sharing from genetic resources that range on their lands. Where land claims have not been settled there is a potential role for ABS-related issues to be reflected in government/industry resource and land management practices. There are many cases in Canada (often through environmental assessment processes) where governments and industry are integrating the interests/rights of local indigenous communities into resource management practices. On the other hand, there are also some cases where Aboriginal people have expressed their concerns that traditional knowledge provided to governments led to the creation of protected areas, but the Aboriginal people were subsequently excluded from continuing their traditional harvesting practices or this secret traditional knowledge submitted to governments was disclosed to others, resulting in non-Aboriginal outfitters beginning to hunt or fish in traditional harvesting areas.

Possible objectives of such *sui generis* protection of traditionally-used genetic resources may include, *inter alia*:

- Community-level participation through a community-based prior informed consent system;
- Continued access and use of traditionally-used biological resources by indigenous and local communities;
- The preservation of traditional knowledge of *in situ* biodiversity including support for traditional protocols governing traditional knowledge;
- Integration of ABS-related issues into government/industry land and resource management practices;
- Where necessary to protect and encourage customary use of biological resources, exclusive use by indigenous and local communities of traditionally-used biodiversity;
- Prohibitions against the use of sacred knowledge, plants or medicines by others, and
- Benefit-sharing at the community-level when traditionally-used biological/genetic resources are used for scientific and commercial purposes.

Sui Generis IP Protection

There are a couple of areas of intellectual property law that are more readily adaptable to protecting genetic resources and associated traditional knowledge. IP systems use fixed term market exclusivity to encourage investments in innovation and generic copies upon the expiration of the term of protection. The concept of fixed term protection has limitations when applied to the objective of conserving biodiversity and preserving traditional knowledge. Conserving genetic resources and traditional knowledge for only a 10 or 20 or 50 year term of protection is not optimal from a biodiversity policy perspective. Trade secrecy, marks and fair trade practices are not constrained in their usefulness in the same way as intellectual property rights with fixed term protection (e.g. patents).

In particular, adapting Appellations of Origin to both genetic resources and traditional products produced by indigenous and local communities would seem to be the most promising opportunity to utilize *sui generis* IP systems to achieve CBD objectives. Adapting appellations of origin type protection to address the issue of follow-on innovation may also be needed to ensure fairness and benefit-sharing from the use of genetic resources and associated traditional knowledge.

Another area of *sui generis* IP protection that can be applied to genetic resources and traditional knowledge is data protection for confidential business information. Data submitted by companies to government regulators can be protected from public disclosure under various regulatory laws. In this way, traditional knowledge submitted for environmental assessments can be protected from public disclosure and the secrecy of the location of harvested plants and animals thereby maintained. A potential model for the protection from public disclosure of traditional knowledge submitted for ABS purposes is that used in some countries such as New Zealand to protect sacred sites. Under such a system, traditional knowledge could be submitted to the government and held as confidential information, only to be used by the government to protect sites containing biological/genetic resources used by indigenous and local communities when they are under threat from resource development or harvesting by others.

There may also be some merit in exploring whether a form of protection for taxonomic data should be considered as part of the international regime. Only 10% of the species on Earth are known, so clearly there is a need to provide public S&T expenditures and/or private sector incentives to accelerate the process of taxonomic research. Knowledge of species is a necessary condition of valuing their uniqueness and building public policy support for conservation of biodiversity. Society is unlikely to value that which it doesn't know exists. There are strong arguments for keeping taxonomic knowledge in the public domain but there are equally strong arguments that greater incentives are needed to encourage taxonomic research. One solution under the international regime would be to link genetic resource and taxonomic knowledge into *sui generis* protection that affords stronger protection for genetic resources that are known, described and publicly disclosed than the protection afforded to unknown in-situ species.

Another possible form of *sui generis* IP protection would entail the Convention of Biological Diversity owning a world-wide certification mark through ownership of national certification marks in key countries. The CBD would then become a standards setting body that would establish rules for use of this certification mark. This hybrid instrument could meld aspects of intellectual property and CBD objectives (including ABS) into a *sui generis* system. The merit of such a proposal may depend on the scope of the rules that Parties would establish for such a certification system and whether these may be legally-binding obligations related to user measures and enforcement.

Non-IP *Sui Generis* Protection

Although many of the potential elements to be considered in the development of sui *generis* systems for the protection of traditional knowledge (in the annex of COP7/16) match those of WIPO's elements for *sui generis* intellectual property protection, a key difference can be found in paragraph 4 concerning customary law. It is important for this discussion to restate this potential non-IP element:

> Recognition of elements of customary law relevant to the conservation and sustainable use of biological diversity with respect to: (i) customary rights in indigenous/traditional/local

> knowledge; (ii) customary rights regarding biological resources; and (iii) customary procedures governing access to and consent to use traditional knowledge, biological and genetic resources.

This paragraph illustrates the central philosophical difference regarding the protection of traditional knowledge that exists between the World Intellectual Property Organization and the Convention on Biological Diversity. WIPO views traditional knowledge through an IP lens the philosophy underlying the objectives and nature of intellectual property rights. To be protected under *sui generis* IP law, traditional knowledge will need to be adapted to fit into this legal structure.

On the other hand, Article 8(j), and related provisions, affords an opportunity to develop *sui generis* systems of protection recognized under national law that resemble the customary laws/traditional protocols of indigenous and local communities. A key goal of any such *sui generis* regime is to support the conservation of biodiversity and preservation of traditional knowledge as compared to the overarching goal of intellectual property rights which is to foster innovation, creativity and commercial use.

In practice, the subject matter of non-IP *sui generis* systems may closely resemble that of intellectual property rights. The customary laws/traditional protocols of indigenous and local communities provide rights and obligations covering names and symbols, textile designs, medicines, songs, dances, stories, etc.

Conceptually, I see non-IP *sui generis* regimes having two faces. One face will be recognized by indigenous and local communities since measures consistent with customary laws/traditional protocols will apply at the community level. The other face will be recognized by marketplace participants as having some elements of intellectual property protection such as market exclusivity rights and redress through the courts when there is unauthorized use of traditional knowledge.

New Forms of *Sui Generis* Protection

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Some Initial Reflections

Patents, copyrights and other currently existing intellectual property formulations are inadequate in providing positive protection for TK, and in some ways also make defensive protection more difficult. This does not mean their use should never be considered, but that their limitations are fairly severe and we might as well accept that as given. Apart from the basic conceptual and practical challenges in applying western formulations of intellectual property to TK, for many traditional societies the incompatibilities go very deep indeed.

Consider the views of Brazilian shamans from 20 indigenous tribes that met in São Luis, Maranhão in December 2001. Among a set of recommendations and proposals on the theme of "Indigenous Knowledge and Science and Industrial Property" that they published in a letter, the following passage stands out:

> As traditional indigenous peoples who inhabit diverse ecosystems, we have knowledge about the management and sustainable use of this biodiversity. This knowledge is collective and is not a product that can be commercialized like an ordinary piece of merchandise. Our knowledge of biodiversity cannot be separated from our identities, laws, institutions, value systems and our cosmological vision as indigenous peoples.

For peoples holding such perspectives, the idea that TK can be fragmented, with each "piece" converted into separate units of quite distinct forms of alienable intellectual property, is likely to be completely alien. Consequently, any legal system of protection must somehow accommodate the holistic nature of TK. It must also avoid imposing notions of authorship that are alien to the beneficiary communities. While it would go too far to suggest that innovation and creativity in traditional societies are always collective achievements, they usually are. Even community knowledge specialists such as healers and artists do not necessarily consider themselves to be the creators or authors but rather as intermediaries between the community and the spirit world. On the other hand, the *sui generis* system should not dogmatically vest rights in whole communities that rightly belong to individuals or smaller groups. This could be very divisive. Close collaboration with TK holders and their communities is essential in the design of the *sui generis* system. This point cannot be emphasized strongly enough.

Devising such a system must of course have clear objectives. Three may be derived from CBD Article 8(j): (i) to respect, preserve and maintain traditional knowledge, innovations and practices; (ii) to promote their wider application with the prior informed consent and involvement of the holders; and (iii) to encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices with these holders.

Since CBD Parties agree in principle to these objectives, it seems appropriate that the *sui generis* system should also adopt them. But is this enough? It does not seem rational or even respectful towards TK holding peoples and communities to separate the task of protecting the knowledge from that of maintaining the integrity of the cultures which generate the knowledge. Such an approach is unlikely to work anyway. In this context, the Secretariat of the Convention on Biological Diversity produced a document[1] which noted that in the light of past discussions on this matter, "it is essential that *sui generis* systems:

- Be not only consistent with but supportive of the provisions of the Convention on indigenous and local communities, and conservation and sustainable use of biodiversity;
- Be based on an integrated rights approach guided by human rights principles and concern for the environment;
- Have among their basic objectives:
    - The encouragement of conservation and sustainable use of biodiversity;
    - The promotion of social justice and equity;
    - The effective protection of traditional biodiversity-related knowledge and resources against unauthorized collection, use, documentation and exploitation in part this would require a provision on prior informed consent; and
    - The recognition and reinforcement of customary laws and practices, and traditional resource-management systems that are effective in conserving biological diversity, and
- Be developed in close collaboration with indigenous and local communities through a broad-based consultative process that reflects a country's cultural diversity.[2]

As for the scope and extent of protection, given the existence of the CBD and the particular interest that many countries have in biodiversity-related TK, the system should probably be limited in its coverage to TK associated with biological resources or with the environment more generally. This is not to argue that this particular element of TK should be protected to the exclusion of other elements. But an international consensus is much more likely to be achieved by limiting the scope of protection in this way. After all, many of the discussions and proposals put forward so far focus primarily on biodiversity-related TK.

Putting the National Cart before the Multilateral Horse? Identifying Priorities

Should efforts be devoted to developing a national *sui generis* system first, in order to gain experience that makes it easier to determine what a workable international solution should look like? Or is a multilateral settlement a pre-condition for the effective protection of the rights of TK holders? And what kind of a multilateral settlement is feasible anyway?

While each country will no doubt come up with good reasons to answer these questions differently, the undeniable problem with having a national system in a world where few such systems exist is that no matter how effective it may be at the domestic level, it would have no extra-territorial effect. Consequently, TK right holders would not be able to secure similar protection abroad, and exploitative behaviour in other countries would go on as before.

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[1] Secretariat of the Convention on Biological Diversity (2000), "Legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Note by the Executive Secretary" [UNEP/CBD/WG8J/1/2].

[2] [CBD Secretariat paper] Dutfield, G. 1997. *Can the TRIPs Agreement Protect Biological and Cultural Diversity?* Biopolicy International Series No. 19, Nairobi: ACTS Press.

Dilemma and Dangers

An international *sui generis* system may turn out to be useless or even dysfunctional. Consider that indigenous peoples and traditional communities make up most of the world's cultural, intellectual and jurisprudential diversity. A legal system that works for a group inhabiting a valley in the Upper Amazon may be totally inappropriate for another group in Siberia or even in a neighbouring valley. For a common international regime to provide effective international legal protection in foreign jurisdictions, a certain degree of harmonization would be necessary. And a harmonized system cannot easily accommodate diversity. The result may be a regime that is appropriate to no culture and is therefore useless.

On the other hand, a legal system tailored to the specificities of a few prominent ethnic groups may well alienate other indigenous peoples, constituting another case of globalised localism to be added to intellectual property rights - which are really just European legal models that have been exported around the world including countries and cultures that really have little use for most of them.

A Checklist of Key Points for Negotiating and Policy Making

In conclusion, the following list of key points is provided for the consideration of negotiators and policy makers:

- Act on the understanding that different countries have varied interests and concerns in respect of TK and also that their positions may be based on quite different assumptions and ideological standpoints concerning TK and TK-holding groups;
- Do not expect early solutions to this issue. Devising workable measures and achieving consensus on their adoption will take a long time given the complexity of the issue, the stakes involved and the conflicting interests of the various "stakeholders";
- Avoid or discourage protracted discussions on the applicability of existing IPRs to TK, and on the "need" to define TK first before solutions may be formulated;
- Conduct studies to estimate the costs of implementing proposals or measures to protect TK and weigh these against the benefits that can realistically be gained *before* deciding to actively pursue them in international forums;
- Ensure that national policies and multilateral-level negotiating positions and strategies are consistent, coherent and mutually supporting;
- Encourage the active participation of TK holders and traditional communities in both the formulation of national policies and of multilateral negotiating positions;
- Place the interests of indigenous peoples and traditional communities at the centre of all negotiating strategies on TK, and
- Be aware that many otherwise sympathetic people oppose the creation of new property regimes on the grounds that they will shrink the public domain. Therefore, it may be necessary to emphasize that a *sui generis* system based upon customary law would not enclose part of the knowledge commons but would merely recognise property rights that already exist but which are not respected.

Finally, TK protection for many indigenous groups is likely to work only with secure land rights. Groups empowered with rights to control access to their lands and communities are far better placed to benefit from legal protection of their knowledge. In fact, it is probably indispensable. In many parts of the world, indigenous groups are being expelled from their ancestral lands. Demanding legal protection of their knowledge without doing anything about this problem is futile and also appears rather perverse.

DISCUSSION PAPER
New Forms of *Sui Generis* Protection Relevant for the International Regime (GR and/or TK)

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Summary

Based on previous discussions in the CBD and other international processes, this issues paper contains reflections on possible new forms of protection for traditional knowledge associated to genetic resources (TK), as identified in Element (xv) of the Terms of Reference for the elaboration of the International Regime (IR).[1] These reflections are guided by the conclusions of the Working Group on Article 8(j) and the COP, that the most appropriate protection for traditional knowledge would be "*based on a combination of appropriate approaches, ... including the use of existing intellectual property mechanisms, sui generis systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice.*"[2] This paper offers possible means of operationalizing such a "combined approach to TK protection" by drawing upon unfair competition law; access and benefit-sharing models as set out in the Convention; compensatory liability schemes; and the recognition of customary laws and understandings. The paper elaborates these four legal tools and suggests that they could be combined and coherently applied within the umbrella of existing unfair competition law. As many TK holders and international policy processes have suggested, this broader approach might be more appropriate to the needs expressed by TK holders than one based purely on private property rights. Finally, the paper refers to some operational frameworks at national and international level, which already apply elements of this 'combined approach' and might be of interest in the elaboration of the IR.

Background

Decision VII/19D sets out the Terms of Reference for the elaboration of the International Regime for Access and Benefit-sharing (IR) and specifies, *inter alia*, that:

- the scope of the IR would include "traditional knowledge, innovations and practices in accordance with Article 8(j),"[3] and
- elements to be considered for inclusion in the IR include "recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located."[4]

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* The views expressed in this paper are exclusively those of the author and do not necessarily reflect the views of the World Intellectual Property Organization, its Secretariat or its Member States.

[1] See COP Decision VII/19D, Annex, paragraph (d), Element (xv)

[2] CBD COP Decision VI/10A, para. 33.

[3] Decision VII/19D, Annex, paragraph (c)(ii)

[4] Decision VII/19D, Annex, paragraph (d), Element (xv)

From these elements, a number of implications would seem to follow for the process of elaborating TK protection in the context of the IR, which are taken into account in this paper. These include that:

- direct and effective participation of indigenous and local communities is indispensable for the development of adequate forms of TK protection;
- the international regime would need to take into account numerous *sui generis* TK laws which already exist at the national and regional levels;[5]
- for TK protection under the IR to function effectively, there should be international comunality with other legal instruments and systems (such as the farmers' rights provisions under the ITPGR, existing IP systems, indigenous rights instruments, etc), and
- given the concerns which TK holders have expressed towards the use of existing intellectual property rights for TK protection, an approach which is broader than a regime strictly based on private property rights would probably be most adequate in the context of the IR.

The next section sets out possibilities for developing such broader protection beyond exclusive property rights. It begins the development of such options with the concerns and priorities that have been expressed by TK holders.

Needs and Concerns to be Addressed

During a decade of international discussions on TK policy, indigenous and local communities have consistently articulated at least four main concerns which lead to a demand for legal protection:

- preventing the misappropriation of TK through illegitimate third party IP rights;
- application of prior informed consent principles;
- equitable benefit-sharing, and
- respect for the cultural and spiritual values of TK, including customary laws and understandings.

While there are numerous other concerns expressed by TK holders, these are four persistent themes that have marked the demand for legal protection. As regards the form of protection itself, the discussions have distinguished between two types of TK protection:

- defensive protection: which refers to the safeguarding against illegitimate third party IP rights over TK; and
- positive protection: which refers to the protection of TK through the recognition of rights in TK.

A Combined Approach to TK Protection

In Decision VI/10A, the COP recommended that the most holistic and comprehensive way of meeting these multiple concerns of TK holders was:

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[5] Examples include the *sui generis* laws and measures for TK protection developed by the African Union, China, Costa Rica, India, Peru, the Philippines, Portugal, Thailand, and the United States of America. A comparative analysis of these laws and measures is included in document WIPO/GRTKF/IC/5/INF/4.

> based on *a combination of appropriate approaches*... including the use of existing intellectual property mechanisms, *sui generis* systems, customary law, the use of contractual arrangements, registers of traditional knowledge, and guidelines and codes of practice.[6]

In fact, a comparative analysis shows that most existing *sui generis* laws already use a combination of legal and conceptual tools for TK protection. In a comparative analysis of ten *sui generis* laws and measures, which are already in force in most countries (available as WIPO/GRTKF/IC/5/INF/4),[7] I found that the majority of laws rely on various combinations of five basic policy tools. These five approaches could also serve as possible policy tools for the international development of TK protection which meets the diverse needs of TK holders:

- unfair competition law;
- PIC principles and mutually agreed terms (ABS mechanisms);
- compensatory liability rules;
- references to customary laws and understandings of TK holders during the application of all the afore-mentioned tools, and
- optional use of property rights, if and when chosen by TK holders and subject to national law and policy.

Through a selective and coherent combination of these legal tools a customized form of protection could be constructed which could seek to provide: improved defensive protection; appropriate application of prior informed consent principles; improved benefit-sharing for industrial and commercial uses of TK which are undertaken with gainful intent; and a sensitivity towards customary laws and understandings of TK holders.

The next part of the paper describes each sof the legal and policy tools and indicates how they relate to the concerns to TK holders, the Terms of Reference for the IR negotiations, and existing national and international legal systems.

Possible Policy Tools for a Combined Approach

The five tools mentioned above can be used in any combination. They are not mutually exclusive, nor are they necessarily mutually dependent. For example, the *sui generis* measure of Brazil combines ABS mechanisms with the grant of exclusive rights; the laws of Costa Rica and Portugal combine ABS models, exclusive rights and unfair competition law; Peru uses ABS elements, unfair competition law and recognition of customary laws; the USA uses unfair competition law and exclusive rights. On the other hand, some countries use only a single policy tool for their TK policy, such as China (exclusive property rights), India (ABS mechanisms), and Thailand (exclusive rights).

It is important to recognize that these are conceptual distinctions, which do not necessarily coincide with operational imperatives. This means that if several tools are used in a law, it does not imply that there are multiple protection systems in that jurisdiction, or that the single system is necessarily very complicated. Rather it means that the legislation is truly customized (*sui generis*) and combines different conceptual components in its construction of a singular operational system. For example, in the Peruvian Law or the African Model Law, multiple conceptual tools may be employed in a single provision setting out combined forms of protection.[8]

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[6] CBD COP Decision VI/10A, para. 33.

[7] These were the *sui generis* laws and measures of the African Union, Brazil, China, Costa Rica, India, Peru, the Philippines, Portugal, Thailand, and the United States of America.

[8] See Title VII, Law No. 27811 of Peru and Art.16, African Model Legislation.

Repression of unfair competition

Several existing *sui generis* laws employ elements of unfair competition law to protect TK. For example, the Peruvian *sui generis* law has taken elements of repression of unfair competition and applied them to TK. In fact, the drafters of this law reported that "the so-called general clause used in the repression of unfair competition inspired the scope of protection granted by this Law".[9] The Portuguese Law creates a link between *sui generis* frameworks for TK and unfair competition law, including the registration of geographical indications and appellations of origin.[10] The Indian Arts and Crafts Act of the USA applies a truth-in-advertising approach to the marketing of indigenous craft products.[11] Additionally, surveys have shown that numerous countries use their conventional unfair competition laws to protect TK (eg., Hungary, Peru, Portugal and the Republic of Korea).

While the repression of unfair competition has been recognized, since 1900, as an object of industrial property protection under the Paris Convention[12], it does not grant exclusive rights over intangible property to the right holder. Unfair competition law is potentially broad in scope, and has been used in international instruments as a basis for protection of layout designs of integrated circuit, geographical indications, undisclosed information, and phonograms.

ABS models (PIC and mutually agreed terms)

Many *sui generis* TK protection measures form part of national access legislation for genetic resources and therefore apply ABS mechanisms (i.e., PIC and mutually agreed terms) to traditional knowledge. Examples include the *sui generis* laws of the African Union, Brazil, Costa Rica, India, etc. This reflects a tendency in national access laws to apply the spirit of Article 15 CBD to TK, which implies that TK held by a community should not be accessed, recorded, used or commercialized without the PIC of the TK holder.[13] Detailed guidance on the Elements and Basic Principles of PIC systems, including their application to TK are contained in the Bonn Guidelines.

Compensatory liability

One further option are compensatory liability rules that grant a 'right to compensation' for commercial follow-on uses, but not a right to prevent such follow-on uses.[14] Such proposals entail an entitlement to compensation, but no right to block TK from further use. Such a rule is a "use now, pay later" system, according to which the use of TK is allowed without the authorization of the right holders, but an ex-post compensation is required for industrial and commercial uses (of a certain time period) if the TK provides a technology-based advantage to the user. The Peruvian *sui generis* law already utilizes similar rules to reward conservation and development costs invested by the communities in certain TK elements, without endowing exclusive property rights to control such uses.[15] It combines the equitable reallocation of benefits without constraining open access to know-how.

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[9] Peru (WIPO/GRTKF/IC/5/INF/6, Annex V, para. 49).

[10] The sixth preambular paragraph of the Portuguese GRTK Law states that « The description of this material [i.e., genetic resources and associated TK], the identity of which shall be defined in *sui generis* terms ..., further reinforces the grounds for formulating processes with which to protect appellations of origin and geographical indications and affords some kind of protection against any misappropriation of the material. »

[11] See, for example, the Indian Arts and Crafts Act of 1990 of the United States of America.

[12] See Art.1(2) and Art.10*bis*, Paris Convention.

[13] See WIPO/GRTKF/IC/6/INF/4, para.4(a)

[14] See, Reichman, J., 2000. *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*. Vanderbilt Law Review, Vol. 53, no. 6, p 1743.

[15] See Peruvian Law No. 27811 of August 10, 2002.

Exclusive property rights

Exclusive property rights in protectable elements of TK can be made available through (i) conventional forms of IP rights; (ii) amended forms of existing IP rights; or (iii) new *sui generis* rights which are tailored to suit the characteristics of TK subject matter and the interests of TK holders. This is the mechanism most associated with IP policy and legislation, and is common to most forms of IP protection, although other mechanisms (moral rights, rights to equitable remuneration or other compensation) are also part of the broader architecture of the IP system.

Customary laws and protocols

With each of these possible policy tools special attention must be given to the recognition of customary laws and protocols, which functions as a cross-cutting interface with local legal systems in all the above-mentioned tools. A number of existing *sui generis* systems utilize references to customary laws and protocols as an alternative or as a supplement to the creation of modern IP rights over TK. The substantive use of customary laws ranges from obtaining Prior Informed Consent for access to TK "in accordance with customary laws" (Philippines), over the settlement of disputes arising among indigenous peoples in the implementation of TK protection (Peru), to the identification, interpretation and ascertaining of "community, knowledge or technology... under their customary...law" (African Model Law).

Based on existing sui generis frameworks for TK protection, this part of the present paper reviewed various policy tools which could potentially form elements for a combined approach to TK protection, as recommended by the COP. The final part offers possibilities of how these different elements could be integrated and coherently applied in a combined approach.

Integrating the Tools: Unfair Competition Law and the Misappropriation Doctrine

One possibility for combining these policy tools in a coherent framework could be to use unfair competition law for integrating them. Unfair competition law protects the outcomes of a person's intellectual activity not by creating a private property title over the knowledge, but by defining acts of unfair competition which are prohibited in relation to those outcomes. History has shown how lists of prohibited unfair acts can be expanded over time to suit new circumstances and new needs of the knowledge holders. Unfair competition law is thus a flexible and fertile ground for the creation of *sui generis* protection for new types of subject matter, such as layout designs of integrated circuits, confidential information and test data, etc. This can be clearly seen in the progression from the Paris Convention (1967) to the TRIPS Agreement (1994), where unfair competition principles were extended towards the protection of undisclosed information, geographical indications, etc.

This flexibility of unfair competition law derived *inter alia* from the manner in which the Paris Convention (1967) sets out international standards of unfair competition law. Article 10*bis* Paris proceeds in three steps in establishing key features of unfair competition law:

- first, it establishes a basic norm to suppress acts of unfair competition;
- second, it defines "acts of unfair competition" in a non-exhaustive, general way: for example, under Article 10*bis* Paris an 'act of unfair competition' is defined as any act "contrary to honest practices in industrial or commercial matters." In this context, the meaning of "honest practices" is left to national interpretation and thus leaves flexibility in this branch of the law, and
- third, the Convention lists particular 'acts of unfair competition' which shall be prohibited: for example, under Article 10*bis* Paris such particular acts include creating confusion on the marketplace, false allegations to discredit a competitor, indications which are liable to mislead

the public on certain aspects of traded goods, etc. Over time these lists have been expanded to suit new circumstances and new needs of the knowledge holders.

This three-step structure might be useful in creating a coherent framework for the "combined approach to TK protection" outlined above. The remaining part of this paper illustrates this utility by describing possible adaptation of the three-step structure to accommodate a combined approach of TK protection.

In particular, within unfair competition law there is an established doctrine, the so-called "Misappropriation Doctrine," which might lend itself to being adapted to the concerns of TK holders. If the Misappropriation Doctrine were to be adapted, it would be necessary to distinguish between the use of the term "misappropriation" in its precise, technical meaning under the Doctrine ("Misappropriation") and the term's broader, common-day usage in the TK debates ("misappropriation").

Broadly speaking, the term "misappropriation" has been used in the TK debates to refer to the acquisition or use of TK which does not take account of the "main concerns of TK holders" listed above (i.e., illicit third party IP rights over TK; access to TK without PIC; commercial use of TK without benefit-sharing; violation of customary laws and understandings), and which are therefore in violation of the policy tools that were integrated into the combined approach to address those main concerns (i.e., defensive protection; application of PIC principles; compensatory liability and ABS mechanisms; recognition of customary laws and protocols).

Building on a structure analogous to Article 10*bis* Paris, unfair competition law could serve as a framework for integrating references to the various policy tools, by defining "Misappropriation" as "any act of acquisition or appropriation of TK by unfair means", and by leaving the meaning of "unfair means" open to include violation of those policy tools combined under the combined approach to TK protection. Such an approach uses the flexibility of unfair competition law to implement the "combined approach" to TK protection. It does so by adapting the term "unfair means" to the TK-context (as part of the definition of "Misappropriation"). In this context the meaning of "unfair means" is extended to include the violation of any or all the policy tools chosen in the relevant national legislation and contained in the "combined approach to TK protection."

Proposals to use unfair competition law as a tool for TK protection have been proposed by China, the EC, GRULAC, Japan, the South Asian Association for Regional Cooperation (SAARC), the Southern African Development Community (SADC) and the United States of America; by other intergovernmental organizations, such as UNCTAD and the Commonwealth Secretariat;[16] and by policy analysts such as ICTSD and the South Centre.[17] Given this broad support, a set of draft provisions, containing 'policy objectives and core principles for TK protection' which implement such a combined approach, have been issued by WIPO last month (see Annex 1, document WIPO/GRTKF/IC/7/5).

Using unfair competition law this way might make it possible to combine these legal and policy tools in such a manner that:

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[16] See Report of the *UNCTAD/Commonwealth Secretariat Workshop on Elements of National Sui Generis Systems* (February 4 – 6, 2004): page 13 ("Tort of Misappropriation"). See also page 25, proposing an international protocol to prevent misappropriation.

[17] For example, the suggestion that a misappropriation regime should incorporate the law of unfair competition is suggested by Dutfield, G., 2002. *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation*. UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development: see chapter on 'Misappropriation regime' (page 30).

- misappropriation of TK is repressed as an act of unfair competition;
- equitable distribution of benefits arising from commercial or industrial uses of TK is fully ensured through multiple mechanisms (including compensatory liability as well as ABS models, based on PIC and MAT);
- prior informed consent is applied to TK in harmony with existing legal systems at national and international levels;
- TK holders retain full involvement and control in TK protection procedures;
- full flexibility is retained for national authorities to give effect to the regime in a manner compatible with their own legal systems, national policies and stakeholder needs;
- there is no prejudice to the application and availability of existing IP rights in the field of TK (for example, in 2001 China granted more than 3000 patents for Traditional Chinese Medicine inventions);
- defensive and positive protection of TK are fully integrated;
- registration of TK in databases is not required (but possible if so decided by the TK holders);
- national authorities may nationally grant private property rights (*sui generis*) for TK, according to their own legal systems and national policies and stakeholder needs;
- the protection is *sui generis*, but consistent with existing IP principles and other relevant legal doctrines, and
- existing national and regional TK laws would be consistent with such an international regime.

D: Indigenous perples: Community - level PIC for Accessing TK and Genetic Resources, Feasability and good Practices

Customary law as the basis for Prior Informed Consent of Local and Indigenous Communities

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The development of national and International law and policy on ABS is inextricably linked to the development of appropriate law and policy to recognize and protect the rights of indigenous peoples and local communities over their traditional knowledge (TK). There is a growing tendency to require prior informed consent of indigenous peoples and local communities for access to genetic resources on their land as well as to TK. It is also increasingly recognized that customary law and practice of indigenous peoples and local communities has a key role to play in defining the manner in which PIC procedures should be applied. This paper seeks to highlight the importance of customary law and practice for the realization of the three objectives of the CBD and to identify a research agenda to help define modalities for ensuring the effective recognition, respect and enforcement of customary law in any international regime on ABS.

PIC of Indigenous Peoples and Local Communities

The Convention on Biological Diversity established the moral if not the legal basis for requiring prior informed consent (PIC) of local and indigenous communities for access to and use of their traditional knowledge, innovations and practices relating to biological resources. The Bonn Guidelines went further stating that PIC of indigenous and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained. Experience in the development of regional and national ABS laws has tended to take the approach that ABS and TK issues must be dealt with in tandem, and to recognize an obligation to seek PIC of indigenous and local communities as a condition of access to use of genetic resources on their territories and to traditional knowledge. Such is the case with the Andean community Decision 391 and the African Model Law.

Requirements for PIC of local and indigenous communities, has been established at the national level by various different instruments, including constitutional law (Venezuela), national indigenous rights law (Philippines), as well as under laws for the protection of rights over traditional knowledge (Peru) and folklore (Panama). Rights of communities to PIC also arise under ILO Convention 169, which requires consultation prior to the granting of exploration and exploitation rights over natural resources. All of these instruments recognize, in varying degrees, a role for customary law of indigenous peoples in the regulation of access and/or the resolution of disputes relating to the use of resources and/or knowledge.

The applicability of customary law and practice for natural resource management in general, and for ABS and protection of TK in particular, is even more widespread. In many parts of Africa, Latin America, Asia and the Pacific region, constitutional and national law recognizes a role for customary law in issues covering natural resource management and land and marine tenure. In the Pacific region, for example, upwards of 80% of land and a significant portion of coastal and marine areas are subject to traditional tenure rights. Likewise in this region, rights over both biological and genetic resources are subject to customary law rights. It can be seen, therefore, that under such circumstances ABS issues must be governed with due respect for, and compliance with, customary law. Furthermore, it is clear that customary law is closely linked to traditional resource management.

In Search of Mechanisms for Protection of TK

In the development of TK regimes there has been a tendency to focus on developing mechanisms to control the scientific and commercial use of TK, with the apparent aim of enabling indigenous and local communities to capture the anticipated benefits of the commercialization of TK. This has often conflicted with the expressed desire of indigenous and local communities to protect the integrity of traditional knowledge, as part of their cultural heritage, rather than allowing it to become another marketable good.

Despite its capacity to regulate local resource and TK use, it is immediately clear that limitations upon the enforcement of customary law and practice outside areas under the control of indigenous and local communities, reduces its effectiveness for protecting rights over traditional knowledge. Similarly, the capacity of national law to extend protection to traditional knowledge, which has found its way beyond the area of control of indigenous peoples, is limited to the frontiers of national jurisdiction. Regional initiatives, such as those of the Andean Community, Organization of African Unity and the South Pacific Forum may provide for a further extension of rights but once again these are limited. This highlights the need for a global response, establishing clear recognition and respect for links between customary laws and the various levels of national, regional, and international law.

The multiplicity of existing customary law regimes would make it impossible to identify a specific body of rules, which could apply to all cases. The Four directions Council, a North American indigenous organization, states:

> Indigenous peoples possess their own locally-specific system of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the rights and responsibilities which attach to possessing knowledge, all of which are embedded uniquely in each culture and its language. Rather than trying to establish a one size fits all IP regime to protect traditional knowledge the Four Directions Council proposes that governments agree that traditional knowledge must be acquired and used in conformity with the customary laws of the people concerned

This demonstrates the need for the development of a flexible international regime providing the security of an enforceable system of protection for the rights of local and indigenous communities, while ensuring respect for and compliance with a variety of differing systems of customary law and practice.

To achieve the objective of protecting and strengthening traditional knowledge and innovation systems, in the most appropriate and effective fashion, it will be necessary to identify:

- The objectives of protection;
- Threats faced by traditional knowledge and innovation systems;
- Potential mechanisms for securing protection;
- Priorities of the custodians of traditional knowledge, and
- Potential mechanisms for securing wide protection in a manner that enhances, respects and conforms with customary law and practice.

Building Bridges between Indigenous Customary Law and Practice and National and International Legal Regimes

Presently, in the majority of cases, where customary law conflicts with domestic law the latter prevails. The exception being when a national law can be shown to conflict with constitutionally recognized customary rights. In such cases the aggrieved party will still need the authorities to amend the offending legislation, and to take such remedial measures as may be required to redress any wrong doing. Sometimes, there may be little hope of redress where irreversible exploitation of resources has occurred. Where no constitutional protection exists, communities will forever be dependent upon the goodwill of the national authorities, as legislative action can at any time result in the abrogation of ancestral rights.

Customary law and practice may be undermined by the adoption of culturally insensitive national laws. Similarly, traditional authority is being eroded as those unhappy with their decisions seek recourse to alternative decision-making authorities, or judicial review, both a cause and a symptom of the break down of community social structures.

The challenge for ongoing processes is to come up with systems for defining ownership and "responsibility" under law in a culturally sensitive and appropriate fashion, without leading to an erosion of confidence and security for communities. Where indigenous peoples rights are defined in a constitutional framework which is completely alien to them, analysis of their rights, rather than proving protective and enabling, becomes a form of cultural and legal domination (Glenn 2000). Likewise, indigenous peoples are not empowered when placed in the dilemma of being forced to defend their collective rights in a legal, textual and interpretative context so foreign to their own social or political context, that simply making a claim requires accepting the dominant cultural and conceptual framework (Turpel 1990). The challenge for legislators at both the national and international level is therefore to encounter means to respect and protect indigenous rights in a culturally appropriate and legally effective manner.

Terri Jenki, in a comprehensive work on protection of Australian indigenous peoples cultural heritage, argues that it is not merely a matter of recognizing the uniqueness of indigenous culture but of respecting it and understanding that indigenous knowledge and western knowledge are two parallel and equal systems of innovation. Furthermore, she contends it must be recognized that indigenous customary law and the existing Australian legal system are two parallel systems of law, both of which need to be given proper weight and recognition (Jenki 1998).

While recognition and respect for customary law and practice is considered fundamental for securing the conservation and sustainable use of land and marine ecosystems, where such laws conflict with basic human rights, there is a need to develop meaningful processes to promote the progressive phasing out of infringing practices. In the process of advocating the rights of local and indigenous communities to govern their own affairs (utilizing customary law and practice), an opportunity exists to promote respect for human rights although care must be taken to ensure that in the name of human rights protection, the fundamental rights of communities are not arbitrarily overridden.

Proposals for the codification of customary law and practice have arisen in a number of forums, including the WIPO IGC. This is something which requires careful consideration as to do so would affect the flexibility of customary legal regimes and could have negative impacts for the long term protection of indigenous rights. Consideration of the experience of native title issues in Australia provides a salutary lesson with regard to this proposal. Commenting upon proposals for the codification of customary law based upon the Australian experience, long time aboriginal activist, Mick Dodson, has warned that the codification of rights may signify the first step towards their exhaustion. This occurred with the Native Title Act, where the development of the principle of exhaustion of rights resulted in many aboriginal peoples losing their land rights. Opposition also exists amongst communities in South Pacific Island States where traditional tenure is linked to the ability to narrate genealogies. Disclosure is seen as akin to giving away ownership, and communities frequently display reluctance to the codification and sharing of this information for fear this will compromise rights.

While awareness of the intrinsic, economic, social, environmental and cultural value of traditional knowledge has grown there has been little research of the links between ABS, TK, customary law and practice, and traditional territorial rights as defined in traditional land tenure. To this end, a study of the experiences of indigenous and local communities with regards the recognition and protection of their rights over their TK, lands and resources, may provide some guidance for legislators at all levels, and a means for respecting customary law and practice. Drawing from practical experiences, both successful and otherwise, it may be possible to identify those measures, which enhance the efficacy of the interface between customary law and national, regional and international law.

A comparative study of the underlying principles of customary law and practice may assist in identification of general concepts, which may in turn help define a body of equitable principles to assist in the resolution of disputes relating to access to genetic resources and TK. Further research questions are considered in the attached annex.

Conclusions

The links between national governance and customary law, traditional knowledge and customary land tenure, will require in-depth comparative analysis if best practices for the development of interfaces between differing legal regimes are to be identified.

Any such study should not limit itself to merely considering the modalities for the protection of traditional knowledge, and the development of mechanisms to control the commercial and scientific use of TK. Rather, what is required is the adoption of a wider and more expansive view of the nature, role and values of traditional knowledge and its relationship to traditional resource management systems, with a view to determining the internal and external factors which are placing strains upon traditional knowledge and innovation systems, as well as those which are conducive to their protection and continuing development.

Consequently, it is proposed that there is need for a wide ranging comparative study of the mechanisms for securing the protection and strengthening of traditional knowledge and innovations systems, through the development of effective interfaces between national and international legal regimes and customary law and practice. Furthermore there is a need to gear such study towards the investigation of modalities for enhancing the adoption of national policy to promote respect, understanding and promotion of TK, as well as the strengthening of traditional resource management systems and customary land tenure.

Annex

Developing a research agenda

In order to advance the debate on issues relating to the role of customary law and practice in ABS regulation, there is a need for a more concerted effort to promote the necessary research —and most importantly research by indigenous and local community experts— into issues such as:

- What framework of national legislative, administrative and policy measures is most conducive to ensuring the full and effective recognition and respect for the implementation, jurisdiction and effective implementation of customary law and practice?

- What is the correlation between recognition and respect for traditional authority and conservation and sustainable use of resources?
- What is the link between traditional knowledge, customary law and practice and traditional land and marine tenure?
- What is the role of customary law and practice in securing conservation and sustainable use of resources?
- Are there cases where allowing the free exercise of traditional authority and/or customary law and practice may have negative social, cultural, environmental and economic impacts?
- Are there any instances when national law may legitimately intervene in traditional decision-making processes in order to ensure social, economic, cultural or environmental rights?
- Where must a line be drawn between protection of human rights and the right to freely apply traditional authority and customary law and practice?
- What conditions are necessary for the functioning of a stand-alone system of customary law and practice?
- What conditions lead to the deterioration of traditional decision making authority?
- To what extent are non-codified customary law regimes susceptible to manipulation by incumbent authorities?

Indigenous and Local Communities: Community-level Prior Informed Consent for Accessing Traditional Knowledge and Genetic Resources

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This paper will consider various questions regarding access to genetic resources and related traditional knowledge with an effort to reflect common issues of concern raised by various First Nations peoples in Canada. The comments contained in this paper are only my own observations and should not be considered authoritative of anything other than my personal opinion.

It is my perception that what we are struggling with is a difference in philosophies. While participants at this conference may have expected concrete proposals for resolving what at first blush may be posed as simply an issue of process, I would argue that without understanding the underlying philosophical differences it will be impossible to address the technical elements of the discussion in a manner that will result in harmony rather than further conflict. In examining the philosophical tenets at play we may be able to devise systems that can resolve conflict for the benefit of all humanity and reflect our collective responsibility to the earth.

The philosophical difference to which I refer is that between a paradigm associated with individualism and the commodification of the earth, and a paradigm that respects the sacred in all things, that acknowledges collective responsibility both for each other and for the world outside of human beings. While this has been ascribed to as a clash of cultures between European and First Nations' world views, the reality is that these views are not necessarily related to racial heritage. For the purposes of this paper I shall use the shorthand of referring to these conflicting philosophies as the modern paradigm and the other as the traditional paradigm. The modern paradigm is focused on trade, commodification of knowledge, and enhancing opportunities for economic gain. It is secular, individualistic, and presupposes human dominance over nature. The traditional paradigm is concerned with sustainability, responsibility and relationships. It is spiritual, communistic, and seeks human harmony with nature. It is generally antithetical to notions of personal property.

The creation of an international regime for access to genetic resources and associated traditional knowledge pits these two paradigms squarely against each other. This is not a new conflict; merely a new battleground. The modern and traditional paradigms have been in conflict in the Americas since 1492, and began with arguments over land and souls. The ABS regime is the latest volley.

To create a prior informed consent system that meets the demands of the modern and traditional paradigms is the struggle to which we must turn our attention. Note that in the case of Canada, prior informed consent models must address not only traditional knowledge, but also access to genetic resources as there are constitutionally protected Treaties that acknowledge First Nations' exclusive jurisdiction over the genetic resources held within their territories. Outlined below are some questions, as posed by the organizers of this conference, and answers that reflect my perceptions of the traditional paradigm.

Question: How is traditional knowledge held by indigenous and local communities in the different regions of the world?

In Canada, the knowledge of the Cree, Ojibway, Blood or Dene, so-called traditional knowledge, is held both privately and collectively. Some information is held privately and shared only in accordance with very strict laws or only with those that demonstrate a particular capacity. This might include knowledge of particular sacred practices or particular skills. Other information is held collectively, to be shared freely and widely. This might include, for example, knowledge of foods, social dances, or art work. Yet other knowledge, though widely known, can be used only by certain individuals or only at certain times. Examples might include a chiefs' song that describes his or her territory that would be sung at particular public events (thus widely known). As the song represents the authority of the chief, however, it can only be sung by that chief. Furthermore, these songs are only the property of the individual chief during the course of his or her time in that capacity and then pass to the exclusive use of his or her successor.

Question: What is the process for obtaining community level prior informed consent in different countries depending on how traditional knowledge is held?

The process for obtaining community level prior informed consent varies from community to community. There are over 50 nations of indigenous peoples in Canada, and it is a disservice to the uniqueness of these nations to impose a homogeneous view.

If I were to suggest there was a common characteristic I would point to the common demand for respect. Many First Nations peoples I have spoken with or have heard speak, talk about the need for respect. Respect for their cultures, for their communities, for their needs, for their humanity. If one is respectful of communities, individuals, of traditions, one will simply have to inquire about what the process is in that community and one will be informed.

Some communities have crafted specific processes that one can read about on the internet (See Appendix). Others would struggle with the request, wishing to discuss the matter internally, perhaps at great length over long periods of time. Yet others may test the inquirer, judging his or her intentions, suitability, or sincerity. Some may refuse to ever offer the information and successive attempts to obtain the information will be rebuffed as disrespectful.

There is no one size fits all approach. Efforts by the non-indigenous community to create a system without the involvement of the First Nations will be rejected with scorn. Efforts to impose such a system will most likely be resisted. The best I can offer is that those that want access to genetic resources and associated traditional knowledge should respectfully inquire of the community whether they are interested in sharing the resource or information.

Question: How can awareness and transparency of community-level prior informed consent processes be fostered?

First Nations have lost a great deal over the years since contact with Europeans settlers, not the least of which is knowledge of their own legal systems. The sharing of traditional knowledge was often governed by highly complex rules. The intervening years of community disruption have created disorder and interfered with the intergenerational transference of knowledge about traditional law, including laws about how knowledge is held and shared. These are oral cultures and thus there is no record other than what the Elders hold in their heads.

Building awareness of community-level prior informed consent processes can best be achieved by facilitating opportunities for the Elders to share their knowledge of the traditional laws, amongst themselves first, and then with increasingly wider circles as they feel comfortable. This will allow the traditional laws to be recollected, examined, discarded if they are not beneficial to modern life, or kept and potentially adopted by others that see the value in the approach.

The issue of transparency is another matter altogether. Just as there is no transparency in Cabinet decision-making, the selection of the next Pope or the price Shell Oil sets for its products there should be no expectation that First Nations should be required to make their decision-making processes public. There is no reason why States and commercial interests should expect otherwise. Although some may choose to allow outsiders to observe some decision-making processes, it is likely that other processes will remain forever closed, as the knowledge under consideration is sensitive and subject to exclusive First Nations jurisdiction.

Question: How can community-level prior informed consent systems be incorporated into national ABS laws and the International Regime?

These systems, once settled upon by the community, can be incorporated into national ABS laws and the International Regime. Whether the systems are incorporated, however, depends on the degree to which others respect the laws by which the First Nations choose to govern themselves. This requires first a sharing of information, as discussed above, understanding the intent of the laws, and then adapting national and international laws to respect the community-level process.

Question: Under a national ABS regime and/or the International Regime what are the potential options for redress if community level prior informed consent is not obtained when accessing genetic resources and associated traditional knowledge?

As any damage done will be damage to the First Nations, it should be First Nations approaches that should be respected in developing systems of redress. Among the concerns that First Nations might raise are ease of access to systems for redress; whether the systems have a logical connection between their processes and desired outcomes; and whether the systems put First Nations interests at the centre of the discussion. The fundamental concern will be with restoring harmony within the community following the wrong done.

Question: What capacity building needs to be undertaken at the community level to develop prior informed consent processes and to ensure benefit sharing through mutually agreed terms?

Capacity building is a two way street. Just as First Nations have a great deal to learn about the modern paradigm, so do those that subscribe to the modern paradigm have a great deal to learn about the traditional one.

First Nations need to learn about intellectual property rights regimes as currently conceived, about the nature of commercial interests, and about the operation of commercial enterprises. They need to understand the processes for developing treaties in the United Nations system and to be able to understand the potential impact on their present interests and opportunities. They also need an opportunity to rebuild their own legal systems as they apply intellectual property regimes.

The non-aboriginal community needs to respect First Nations peoples. The best way to come to respect something or someone is to know more about it. First Nations people need to participate in the discussion about the International Regime, to be involved at the national level in the development of national systems, to share their views and to have those views listened to and treated with respect.

Conclusion

It is only through mutual understanding that there can be a meeting of the minds. A treaty, like any other contract, must reflect a common understanding and agreement. A treaty developed by one side and imposed upon another is a guarantee of future conflict. We have seen the results of an oppressive approach in treaty making for land held by First Nations. Let us not repeat the mistakes of centuries past.

Appendix

Below are examples of processes or principles established by some First Nations in Canada to guide those who would seek to work with the First Nation. Some are specific to particular issues, others are very broad and general. All of these examples are available publicly but may have changed since they were first adopted and cannot be considered authoritative by their inclusion here.

Mi'kmaw Grand Council/ Mi'kmaq College Institute, 2000

Principles and Guidelines for Researchers
Conducting Research With and/or Among Mi'kmaw People

Principles:

- Mi'kmaw people are the guardians and interpreters of their culture and knowledge system- past, present and future;
- Mi'kmaw knowledge, culture, and arts are inextricably connected with their traditional lands, districts, and territories;
- Mi'kmaw people have the right and obligation to exercise control to protect their cultural and intellectual properties and knowledge;
- Mi'kmaw knowledge is collectively owned, discovered, used, and taught and so also must be collectively guarded by appropriate delegated or appointed collective(s) who will oversee these guidelines and process research proposals;
- Each community shall have knowledge and control over their own community knowledge and shall negotiate locally respecting levels of authority;
- Mi'kmaw knowledge may have traditional owners involving individuals, families, clans, association and society which must be determined in accordance with these peoples own customs, laws and procedures;
- Any research/study or inquiry into collective Mi'kmaw knowledge, culture, arts, or spirituality which involves partnerships in research shall be reviewed by the Mi'kmaw Ethics Watch (Partnerships shall include any of the following: the researchers, members of a research team, research subjects, sources of information, users of completed research, clients, funders, or licence holders);
- The Grand Council is the authorized body of the Mi'kmaw people and thus has the right to delegate authority for the Mi'kmaw Ethics Watch;
- All research, study or inquiry into Mi'kmaw knowledge, culture, traditions involving any research partners belongs to the community and must be returned to that community, and
- The Mi'kmaw Ethics Watch shall conduct a fair and timely review of all research conducted among Mi'kmaw people and assess all research processes conducted among and with Mi'kmaw people.

The Selkirk First Nation Self-Government Agreement The Selkirk First Nation and Her Majesty the Queen in Right of Canada and the Government of the Yukon, 1997

"Consult" or "Consultation" means to provide:

- to the party to be consulted, notice of a matter to be decided in sufficient form and detail to allow that party to prepare its views on the matter;

- a reasonable period of time in which the party to be consulted may prepare its views on the matter, and an opportunity to present such views to the party obliged to consult, and
- full and fair consideration by the party obliged to consult of any views presented.

Clayoquot Sound Scientific Panel

First Nations' Perspectives Relating to Forest Practices Standards in Clayoquot Sound
March 1995

6.1.4 Recommendations about Inclusion of First Nations

In its second report, the Panel made the following recommendations to incorporate First Nations' perspectives into standards and practices for Clayoquot Sound (Scientific Panel for Sustainable Forest Practices in Clayoquot Sound 1994b:55):

- Include First Nations representatives at the onset of planning processes for Clayoquot Sound;
- Respect traditional values, spirituality, and *h a h uulhi*, and provide for the traditional resource use and subsistence needs of the Nuu-Chah-Nulth in forest planning and management;
- Incorporate First Nations' forest management practices, which are founded in traditional values and ecological knowledge, and which arise as a result of treaty negotiations, in forest inventory, planning, and management;
- Conduct comprehensive consultation with the Nuu-Chah-Nulth about land use practices as specified in the *Interim Measures Agreement;*
- Define cultural sites more comprehensively according to First Nations' understanding (e.g., including a variety of sacred sites, berry-picking sites,medicine-gathering sites). Use Nuu-Chah-Nulth guidance to undertake research, inventory, and identification of culturally relevant places and resources;
- Recognize the importance and potential of concepts of tribal parks and sacred site reserves in land use planning;
- Restore traditional sites that have been altered or degraded by logging practices ... in consultation with the Nuu-Chah-Nulth;
- Provide for training, education, and meaningful employment of Nuu-Chah-Nulth people in both research and forestry activities to ensure that they benefit from commercial use of resources in Clayoquot Sound;
- Give precedence to traditional Nuu-Chah-Nulth needs for sustenance (the definition of which should be agreed upon by governments and First Nations) over sport fishery, commercial, or other interests outside Clayoquot Sound. Provide for the well-being of wild fisheries before the needs of fish Farming;
- Develop standards that recognize, respect, implement, and enforce the maintenance of cultural and biological diversity recognized in *Agenda 21* and *Guiding Principles on Forests*, in forest management practices; and
- Recognize and take steps to minimize the impact of forest practices on marine ecosystems.

DISCUSSION PAPER

Lessons for ABS: Academic Policies, Community Protocols and Community-level PIC

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In applying prior informed consent (PIC) to access and benefit-sharing (ABS) policies, it is important and useful to remind ourselves of the origins of PIC, its historical situatedness and evolution, and its current application to contexts for which it was not originally conceived. PIC is a principle that is deeply embedded in contemporary law and ethics. It is rooted in respect for individual autonomy and autonomous choice. In ethics, PIC evolved from the concept of "voluntary consent", which emerged in biomedical research ethics in the 1940s (i.e., the Nuremburg Code) in response to human atrocities committed against inmates of concentration camps by Nazi scientists in the name of research.

PIC was originally conceived (in ethics) in reference to the *individual* as a protection from *physical* harm, but it is increasingly being extended to *collective* and *non-physical* contexts. Within Canada, the most notable collective application of PIC is to research and development involving Aboriginal communities. The academic research community has struggled with the conception, application and implementation of community PIC in recent years, and it remains a hotly debated subject. When such a deep disparity exists about a term that is being used more and more widely, it can be helpful to take a step back to understand what it is that we don't understand. This paper will (i) explore how community-level PIC is currently portrayed in academic research policies and how it is understood – or misunderstood – in scientific research, and (ii) attempts to unearth lessons for new ABS policy development.

Within Canada, all university-sponsored research involving humans must abide by a national ethical standard called the *Tri-Council Policy Statement for Research Involving Humans*, which was developed in 1998.[1] PIC (referred to as "free and informed consent") is a fundamental principle of this policy; researchers are required to demonstrate that individuals who participate in research do so without undue influence or coercion, understanding the purpose, risks and benefits involved.

PIC is conceptualized as an *ongoing* process that begins before research is initiated and extends throughout the research process. Further, the *Tri-Council Policy Statement* requires that participant consent can be "withdrawn at any time" (Section 2.2, Paragraph 1), meaning research participants can withdraw their participation from the research and may also be entitled to withdraw their contributions up until that time. Usually evidence of PIC is written, for example a consent form signed by the participant before research begins. In certain cases, PIC could be given verbally or in some other form deemed appropriate to the context. At least in theory, the quality of the consent is considered more important than the form it takes, allowing for culturally-appropriate forms and processes. In practice, however, federal granting councils and university administrations encourage a written form of consent likening PIC to a contractual agreement between researcher and the researched, evidenced by sign-off at the onset of research. A sharp contrast (even irony) exists, therefore, between the intended philosophical rationale behind PIC (i.e., an ongoing process) and the ways it is usually practiced (i.e., upfront sign-off).

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[1] Policy available at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

Section 6 of the *Tri-Council Policy Statement* is specific to research involving Aboriginal peoples. It explicitly acknowledges that "some research involving aboriginal individuals may also involve the communities or groups to which they belong" and that "aboriginal peoples have distinctive perspectives and understandings embodied in their cultures and histories ...[and] a unique interest in ensuring accurate and informed research concerning their heritage, customs and community" (Section 6A, Paragraph 6). The central issue raised in Section 6 is determining "when it is legitimate for researchers to interview individuals in their own right as individuals, without regard to the interests of the group as a whole and without seeking permission from any group authority or spokesperson or, conversely, when the approval of the community as a whole should be required." (Section 6A, Paragraph 10).

The *Tri-Council Policy Statement* currently offers little specific guidance in resolving the issue of collective PIC in an Aboriginal context and is widely recognized as seriously inadequate. An extensive revision for Section 6 is in progress. Meanwhile, the policy currently advises researchers to be familiar with several other existing guidelines for research on Aboriginal communities.[2] The key point to note here is that the current national ethics standard in Canada essentially *defers* to other existing documents that have been created by Aboriginal groups or institutions, organizations, and societies working closely with Aboriginal groups.

In addition to various institutional guidelines, many Aboriginal groups in Canada (and elsewhere) have developed their own local guidelines or protocols for research.[3] Among other things, such as the need for reciprocal trust and respect, these outline community expectations about access to and use of their traditional knowledge and related biological resources by outsiders. Community protocols are increasingly being used in defining relationships between indigenous communities and university researchers, in some cases as a defensive response to the imposition of research, and in other cases as a way to actively encourage research and economic development opportunities. Community-level processes for obtaining consent from Indigenous peoples (e.g., customary laws and community protocols) must be given serious consideration in new PIC policy development, as should the role of tribal committees for reviewing research involving specific indigenous peoples and their associated cultural knowledge and traditional resources.

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[2] The recommended documents are: Inuit Circumpolar conference. *Principles and Elements for a Comprehensive* Council for International Organizations of Medical Sciences. *Arctic Policy*, Alaska, Greenland, Canada; *International Guidelines for Ethical Review of Epidemiological Studies*. Geneva: WHO, 1991; National Health and Medical Research Council of Australia, *Guidelines of Ethical Matters in Aboriginal and Torres Strait Islander Health Research*. Canberra: NHMRC, 1991; American Anthropological Association, *Statement on Ethics: Principles of Professional Responsibility*, Adopted by the Council of the American Anthropological Association, May 1971; American Public Health Association Task Force. National Arctic Health Science Policy. Washington, D.C.: APHA, 1984; American Indian Law Center. Model Tribal Research Code. Albuquerque, 1994; and U.S. Interagency Arctic Research Policy Committee, *Principles for the Conduct of Research in the Arctic*. Arctic Research of the United States 1995;9 (Spring):56-57; Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North*, Ottawa: ACUNS, 1982, reprinted, 1988. Royal Commission on Aboriginal Peoples. Appendix B: *Ethical Guidelines for Research*. Ottawa: RCAP, 1993.

[3] Some Canadian examples are: *Code of Ethics for Researchers Conducting Research Concerning the Ktunaxa Nation; 'Namgis First Nation Guidelines for Visiting Researchers/Access to Information; Tl'azt'en Nation Guidelines for Research in Tl'azt'en Territory; Akwesasne Nation Protocol for Review of Environmental and Scientific Research Proposals; Standard of Conduct for Research in Northern Barkley and Clayoquot Sound Communities*.

At the same time, some issues need to be kept in mind. Many community protocols describe a process for obtaining PIC that includes approval by a band council, tribal council, council of Elders, or tribal ethics committee, in addition to the consent of the individual participant. A template consent form is sometimes included. Thus "community-level PIC" in some protocols may be equated with a gate-keeping function provided by a sub-group within the Aboriginal community. Sometimes this is a respected political body, group of Elders or other community members, but sometimes this is a political body that is divorced from traditional practices and/or not supported by the traditional knowledge holders of the community. In these cases, important questions internal to the community may emerge, such as "who has the right to speak for who" and "who can speak about what"?

Some critics have argued in such cases that instead of creating a collective consent process, a "power over" situation emerges within the Aboriginal community, thereby taking away from individual autonomous choice. This adds a new spin to the key question framed in Section 6 of the *Tri-Council Policy Statement*, essentially turning it on its head. That is, from a community member's perspective, the question may become "when it is legitimate for *participants to be interviewed* in their own right as individuals, without regard to the interests of the group as a whole and without seeking permission from any group authority or spokesperson or, conversely, when the approval of the community as a whole should be required." Resolve of this question through internal decision-making processes is pre-requisite to granting community-level PIC to those outside a community.

While the principle of community-level PIC is a vital element of any new ABS policy, for its implementation to meet the intention, the concept must be vigorously discussed until it is more uniformly understood and agreed by users and providers, both indigenous and non-indigenous. Universities, governments and others who wish to interact "institution-to-institution" with indigenous communities must realize that indigenous communities are not made up of homogenous groups of individuals who always agree on internal protocols and processes. Many indigenous communities will need to be enabled (through provision of time, funds, access to information, building of expertise) to *define for themselves* the concept of community-level PIC and the internal process to achieve it, before an external process can be codified. Even within a given nation, such as Canada, this will undoubtedly lead to a suite of different answers rather than a one-size-fit-all solution. An effective and equitable ABS policy must be able to accommodate and support this complexity.

DISCUSSION PAPER

The road to effective prior informed consent for accessing the traditional knowledge and genetic resources of Indigenous and local communities in Colombia

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Introduction

Fulfillment of prior informed consent (PIC) in countries like Colombia is subject to an effective legal framework that clearly stipulates the property regime over biological and genetic resources and traditional knowledge. By analyzing the Colombian property regimes and the issue of access, gaps, uncertainties and complexities surrounding the effective application of an international regime at the national level will be revealed, specifically with regards to PIC. Finally, indigenous and local community responses to inappropriate access to their resources and the conditions for effective PIC in Colombia will be discussed.

Background: Colombia's Property Regime

Biological Resources

Colombian law clearly distinguishes property regimes applicable to biological resources. Biological organisms can be public goods, private property, state property, or collective property. As public goods, biological resources have distinct characteristics: they can not be commercialized, seized, and the State's rights over them do not extinguish over time. As private property, the owner can use, exploit and commercialize the biological resources. Private property rights are not absolute in Colombia. According to the 1991 Constitution, private property has a social and ecological function. As state property, biological resources are owned by a state institution that can acquire, exploit and sell them and the products thereof. In Colombia, collective property over biological resources is held by indigenous and local communities.[1] In terms of common law, there are no biological resources in Colombia that fall under an open access regime or are considered public domain.

Genetic Resources

The property regime applicable to genetic resources is established by interpreting different laws. The Colombian Constitution establishes that the state is obliged to control the entry and exit of genetic resources. Law 99 of 1993 assigns the function of inventories and control of genetic resources to the Ministry of Environment, Housing and Territorial Development (MAVDT). Therefore, the MAVDT is responsible for preserving and guaranteeing the country's rights over their genetic resources. The

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[1] This includes indigenous, Afro-Colombian and local communities.

1995 Law 164, which ratified the CBD, affirms that the country has sovereign rights over its genetic resources. Article 6 of Andean Decision 391 (1996) establishes that genetic resources have the distinctive characteristics of public goods mentioned above. Accordingly, Colombian courts affirmed in two separate cases that genetic resources in Colombia are public goods.[2]

Traditional Knowledge

Property rights over traditional knowledge have not yet been clearly established in Colombia. Nevertheless, there are two main interpretations regarding the legal status of traditional knowledge. First, traditional knowledge is seen as national patrimony and deserves state protection as public goods, and second, traditional knowledge is considered the collective property of indigenous and local communities. The first interpretation is grounded within copyright law. Article 189 of Law 23 of 1982, although it does not refer directly to traditional knowledge associated with biological resources, states that indigenous cultural expressions, including dances, songs, handicrafts, and artwork, are part of the cultural patrimony. Moreover, the Constitutional Court, referring to the distinctive ways that indigenous and local communities relate to their environment and their traditional practices of resource management and use, declared that these communities are unique cultural expressions and constitute part of the national identity.

More recent laws permit a different interpretation. Law 397 of 1997 on Culture, again without direct reference to knowledge associated with biological resources, guarantees the collective rights of ethnic groups on their cultural creations. Article 61 of the Colombian Constitution protects the rights of creators over their intellectual works. On these grounds, indigenous and local communities are the legitimate holders of property rights over their knowledge, innovations and practices. A different interpretation regarding property rights of indigenous and local communities would imply that the creations of those communities are not, in fact, intellectual creations or that members of those communities do not have the same rights as other Colombian citizens. However, such a view has no validity within Colombian law. Furthermore, Article 7 of Decision 391 recognizes that indigenous, Afro-Colombian and local communities have decision-making rights over their knowledge, innovations and practices associated with genetics resources and the derivative products. The consideration of the knowledge of communities as national patrimony makes sense only in relation with the special protection that the state affords to the ethnic and cultural diversity of the nation.

Problems in the Colombian Legal Regime

The Gaps

The main gap is the absence of explicit laws on PIC in relation to genetic resources and traditional knowledge in Colombia. There are stipulations concerning prior consultation with communities under Law 21 of 1991, which ratified the International Labour Organization's Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries[3]. *Article 6* of the Convention 169 state that government must consult the peoples concerned, through appropriate procedures regarding legislative or administrative measures which may directly affect them. These consultations must be carried out in good faith and using appropriate procedures to the circumstances. The Constitutional Court has affirmed that consultation is a fundamental right for the protection of the ethnic, economic, social and cultural integrity of indigenous and local communities[4]. Similarly, article 76 of Law 99 (1993) states that the exploitation of natural resources has to be carried in a way that does not affect cultural, economic and social integrity of indigenous and local communities. Similar laws exist which pertain to Afro-Colombian communities.[5] In addition to these laws, paragraph of Article 330[6] of the Constitution asserts that exploitation of natural resources in indigenous territories should not have negative impacts on their culture, economy and social well-being.

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[2] Ruling of the Constitutional Court C-317 and Administrative tribunal concept C-977 of 1997

[3] Article 13 of Law 21 of 1991

[4] Ruling SU039 de 1.997. Constitucional Court

Decree 1320 of 1998 regulates prior consultation in Colombia. However, this norm has limitations in guaranteeing the prior informed consent of indigenous and local communities. First, it does not deal specifically with their effective participation in activities for accessing their traditional knowledge and biological resources in their territories. Second, the decree allows for only one consultation meeting, even if there are many other communities involved. Third, when communities from the affected area do not present a certificate of recognition as indigenous communities from the Interior Ministry —today the Ministry of Government and Justice— within a certain period of time, it can be assumed that those communities do not exist and therefore the project can go forward without consultation. Fourth, the norm assumes that communities agree with the prevention, mitigation, control and/or compensation measures undertaken to counteract the impacts of a given project when they do not attend a meeting. This norm does not fully guarantee the communities' right to decide the fate of their own resources.

The principal gap in the existing laws is that they do not call for prior informed consent of indigenous and local communities, only consultation. Moreover, the consultation process in Colombia is oriented more to inform stakeholders about development projects, rather than to achieving agreement or consent to the proposed project.

The Uncertainties

Given the different property regimes applicable to biological resources and genetic resources there is uncertainty in the legal system regarding who owns genetic resources in indigenous territories. If we are dealing with biological organisms, they are considered collective property of the indigenous and Afro-Colombian communities who hold title to the territory. But if we are dealing with access to genetic resources, it is the state who grants permission through the national authority (MAVDT). It is not understood by the communities that they can own the biological organisms but not the genetic information that makes up the animals, plants and other living beings. The property regime of biological resources is even more confusing when indigenous territories overlap with national parks.

The uncertainties regarding property regimes are no less numerous when dealing with traditional knowledge. The two contesting interpretations of property rights on traditional knowledge have already been mentioned. Additionally, even if knowledge or innovations were recognized as belonging to indigenous and local communities, there are still issues to resolve. The law does not have rules to apply when there are different rights holders for example, neighboring communities. Uncertainties on the legal rights on the subjects of access (genetic resources and traditional knowledge) make transaction costs too high or impossible to cover.

The Complexities

The complexities with regard to PIC of indigenous and local communities does not derive only from the property regimes. There are situations that come from Colombia's environmental legislation and the distribution of knowledge within communities that are relevant when considering this problem.

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[5] Law 70 of 1993

[6] Article 330. Paragraph. "Exploitation of natural resources in the Indigenous (Indian) territories will be done without impairing the cultural, social, and economic integrity of the Indigenous communities. In the decisions adopted regarding the said exploitation, the government will encourage the participation of the respective communities representatives."

First, the environmental legislation designated conservation areas under special categories for example, national parks, flora and fauna sanctuaries and forest reserves. Importantly, these protected areas did not take into account the indigenous peoples who inhabited those territories. Many conservation areas have partially overlapped indigenous territories, and in at least two cases, national parks (Macuira and Puinawai) have been completely superimposed upon indigenous lands. In those cases, to obtain access to genetic resources and traditional knowledge would be a real challenge.

Second, the distribution of knowledge within communities is not even. It has been documented that cultural variation in traditional knowledge systems is a distinctive characteristic. Distribution of knowledge has been explained by the social division of labour and socio-demographic variables.[7] Important components of knowledge may be held only by certain individuals like healers or shamans.

Therefore, the overlap of Indigenous territories and protected areas, the several property regimes on biological and genetic resources, and the uneven distribution of knowledge make it quite complex to identify who is entitled to grant consent.

Indigenous and Local Communities' Response

To deal with the inappropriate access to biological resources, genetic resources and traditional knowledge, indigenous communities are adopting various strategies. One is social and territorial control. Through this mechanism, community members are obligated to control and monitor the collection and extraction of biological material and associated knowledge from their territories. Some organizations, like the Indigenous Organization of Antioquia (OIA), have even established regional by-laws regarding research activities on biological resources and traditional knowledge. Another strategy of indigenous communities, like that of the Regional Organization of the Embera Wounaan of Chocó (OREWA), has been to establish their own research centre. This approach affirms that communities themselves can identify the subject of research or appropriate projects that improve their environmental, socio-economic, educational and human health needs. Finally, several indigenous authorities have called for a moratorium.[8] This position puts forth that while no effective guarantee of the rights of indigenous communities over their resources and knowledge exist, there must not be any access to their traditional knowledge and biological resources within their territories.

Conditions for Effective PIC in Colombia

Furthermore and in conclusion, indigenous communities in Colombia have put forward principles for the appropriate and effective granting of PIC. First, there needs to be the legal recognition of their territories. Territorial rights of Indigenous Peoples is fundamental for the continued conservation of biodiversity and for the maintenance of their knowledge, practices innovations and livelihoods. In Colombia, the long standing armed conflict has made life very difficult for Indigenous Peoples and this has had pronounced impacts on the environment. Second, with respect to the right to prior consultation, PIC can not be effective without the reformulation of the Colombian laws on prior consultation. When faced with bioprospecting activities, indigenous communities need to have the opportunity to participate equally so they can actively develop and agree to the terms of access and benefit-sharing. Capacity building is a necessary tool to ensure a more balanced playing field in access negotiations. Third, indigenous communities demand the right to freely make decisions regarding the biological resources within their territories and their associated knowledge. The right to oppose access must be recognized when cultural, socio-economic and/or environmental integrity of indigenous communities is at risk. Finally, indigenous communities demand that their collective ownership of biological resources and traditional knowledge be explicitly recognized in order to prevent misappropriation of their resources. It is critical that access to biological resources and traditional knowledge and implementation of PIC within a perspective of ABS allows indigenous communities to preserve and maintain practices embodying lifestyles relevant for the conservation and sustainable use of biodiversity.

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[7] Studies have shown that gender, age, expertise, ethnicity, and kinship affiliation are relevant in explaining the distribution of cultural information (Boster, 1985, 1986; Ellen, 1975; Boster and Johnson, 1989; Nemogá, 2004).

[8] Access to the Resources of Biodiversity and Indigenous Peoples by Lorenzo Muelas Hurtado (*Movimiento Autoridades Indígenas de Colombia)* 1998. http://www.edmonds-institute.org/muelaseng.html (Last accessed on October 21, 2004)

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E: Measueres to Ensure Compliance with CBD and Access Legislation. Stakeholders, Scientists as Users and Provides, Codes of Conduct/ Awareness

Mechanisms for Compliance with ABS by the Academic Research Community (Canada)

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University scientists are key intermediaries between several different actors. Ethnobotanists, for example, are both investigators and brokers of genetic resources and related traditional knowledge for universities, governments, industry and wider society.[1] Their science takes place at the complex interface of ethics and law, governed by institutional research polices that must incorporate evolving sets of ethical and legal standards at the international, national, and local levels. These institutional research policies are worth examining as a potential mechanism for incorporating new access and benefit-sharing (ABS) policy and facilitating compliance with ABS by the academic research community.[2] This paper focuses on the Canadian context. Each country will have its own policies and institutional structures, which may be quite different than what is described here, so the following analysis should be viewed as one example, perhaps providing a stimulus for similar analysis of university policies within other countries.

In ethnobotanical research there are obvious links between genetic resources and traditional knowledge.[3] Other types of research involving genetic resources may or may not *directly* use traditional knowledge, but there are still often indigenous cultural interests in the research based on traditional uses (either similar or competing), or claims to a given geographical area (e.g., traditional territory) where genetic resources may be collected. Given the inextricable connection between biological diversity and traditional knowledge that is evident in Aboriginal worldviews, it would be prudent (at least within Canada) to assume there are indigenous cultural interests, if not rights, in most research involving genetic resources, whether on ethical, legal or political grounds. Likewise, while some biodiversity research is overtly commercial in nature (e.g., bioprospecting), the goals of academic research are often non-commercial. However, most data flows (directly or indirectly) into the private sector and is available for commercial purposes sooner or later. Therefore, directly or indirectly, intentionally or not, research involving genetic resources and traditional knowledge facilitates knowledge and resource appropriation through research, publication, or sponsorship arrangements, even when the researchers' intentions are purely academic.

University expectations for research (e.g., conceptions of benefits, harms, risks and responsibilities) and application of research policies are influenced by whether or not indigenous peoples are *directly* involved, whether the research is national or international in scope, and whether it is primarily academic or commercial in nature. University research policies that are particularly relevant to research involving genetic resources and traditional knowledge, including: (i) ethics policies for research involving humans, and (ii) intellectual property (IP) ownership policies.

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[1] There is no single agreed definition of "traditional knowledge". In this paper, it refers to the knowledge, beliefs, innovations, and practices based on customary uses and associated cultural practices and traditions of indigenous peoples, usually transmitted through oral tradition and first-hand observation (CBD 1992, Laird 2002).

[2] The academic research community refers to university scientists and graduate students who conduct research, and university administrations that develop and oversee research policies.

[3] Ethnobotany is the study of inter-relationships between humans and plants, most often involving indigenous peoples and their traditional plant knowledge and resources.

Effective national ABS policy must explicitly address the complexity and inter-relatedness of ethical, legal and political considerations in scientific research involving genetic resources and traditional knowledge. But how and at what level should new ABS policy be developed and implemented to facilitate compliance by the academic research community? With this question in mind, this paper examines the existing institutional structures for Canadian University research policies. Two potential areas to target with regards the incorporation of ABS policies into the university system are: (a) national and institutional human research ethics policies; and (b) institutional IP ownership policies. Outside of the university structure, additional target areas include: (c) ethical codes of professional associations and academic societies; and (d) community research protocols. The merits and challenges of these proposals are briefly outlined below.

Human Research Ethics Policies

Existing structures.

Within Canada, all university research that involves humans (e.g., experiments, interviews, surveys) must equal or surpass a national ethics standard called the *Tri-Council Policy Statement for Research Involving Humans,*[4] developed in 1998 and administered through the three federal granting councils.[5] Compliance with the national ethics standard is mandatory for all universities receiving funding from the granting councils. Implementation is at the institutional level, through university research ethics boards (REBs) that review and approve or reject proposals for research involving humans.[6] Most institutions and their REBs make a significant effort to educate researchers about ethical considerations in research and assist them in addressing any shortcomings in their proposals. There is considerable incentive for compliance at individual and institutional levels as depending on the source and severity of non-compliance, federal funding support could be withdrawn from a specific project or the entire university.

Prior informed consent (PIC) (in this case referred to as "free and informed consent") is a key principle of university ethics requirements at the national and institutional levels. In principle, PIC is conceptualized as an *ongoing* process that begins before research is initiated and extends throughout the research process.[7] However, in practice, evidence of PIC typically follows a contractual model, i.e., a consent form signed by individual participants or designated representatives of organizations at the onset of research. Existing policy regarding collective PIC (e.g., some research involving traditional knowledge) is recognized as seriously inadequate and is currently under revision at the national level.[8] Community-level processes for obtaining consent from indigenous peoples (e.g., customary laws and community protocols) are being given serious consideration in new PIC policy development. The role of community-level REBs (e.g., tribal committees) for reviewing research involving specific Indigenous groups is also being given due attention.

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[4] Policy available at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

[5] The three granting councils are the Social Sciences and Humanities Research Council (SSHRC), the Natural Sciences and Engineering Research Council (NSERC) and the Canadian Institutes for Health Research (CIHR).

[6] REBs are typically comprised of university faculty and community members serving in a volunteer capacity, with administrative support provided by the university.

[7] The *Tri-Council Policy Statement* says "consent must be freely given and may be withdrawn at any time" (Section 2, Article 2.2, Paragraph 1), which is interpreted by most institutional REBs as meaning research participants can withdraw their participation from the research at any time. This may also include withdrawing their contributions.

[8] The *Tri-Council Policy Statement* does include a section on research involving Aboriginal peoples (Section 6) but it was not developed with the participation of Aboriginal representatives and so is in abeyance until appropriate consultation has been undertaken. Currently, a major revision is being facilitated by a new national Aboriginal Ethics Working Group (comprised of Aboriginal Elders and scholars, and some non-Aboriginal scientists), coordinated by CIHR's Institute for Aboriginal Peoples Health.

Applications to ABS

In cases where traditional knowledge for biodiversity research is provided by indigenous peoples, ABS policy requirements would overlap with those of existing national human research ethics policies (e.g., PIC requirements, due acknowledgement of source, sharing of benefits). In such cases, the human research ethics aspects of ABS policy could fall under the jurisdiction of the three federal granting councils, either being developed in conjunction with (i.e., as a new section of) the *Tri-Council Policy Statement on Research Involving Humans* or as a separate and parallel *ABS Policy Statement*. Similar to human research ethics, an overarching national ABS policy could serve as the minimum standard for all university research involving genetic resources and traditional knowledge. Compliance would be a mandatory prerequisite to qualify for federal funding. Individual universities could expand their current research ethics policies and review processes to incorporate ABS requirements. Individual research proposals would be approved or rejected by REBs, and researcher awareness would be increased by the educative approach that most universities take in helping researchers to revise non-compliant research proposals.

Benefits would include building on national and institutional structures that are already in place rather than creating new frameworks, as the latter would require significant time and cost. Incorporating ABS issues related to research involving traditional knowledge into human ethics research processes would increase the awareness of the complexity in researcher/institutional/Nation state/Indigenous rights issues in biodiversity research, which could influence wider policy development on PIC and benefit-sharing. Challenges would include the need to educate REBs on new ABS policy and the potential of over-burdening institutional REBs with heavier workloads as these are typically voluntary positions held by full-time faculty and community members. Under current policies, only research that *directly* involved indigenous peoples (e.g., through interviews, surveys) would fall within the realm of human research ethics; research based on published traditional knowledge would not.

Intellectual Property Ownership Policies

Existing structures

In contrast with the national research ethics requirement, which is intended to be implemented consistently across all publicly funded Canadian universities, there is no over-arching IP policy for universities. Each university independently determines its own IP ownership policies, in accordance with Canadian and international law. In general terms, IP ownership policies of most universities may be categorized as "institution as owner" or "inventor as owner". That is, while the researcher is recognized as the creator or inventor, some universities insist on transfer of ownership rights if intellectual property protection (such as a patent) is sought or if an invention is licensed or commercialized.[9] Other universities simply require a sharing of any revenues as compensation for the infrastructure that they have invested in the research and/or commercialization process. Agreements among inventors and between institutions to specify inventorship, ownership, commercial rights and profit sharing are typically contractual in nature, facilitated in-house by university technology transfer offices.

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[9] Copyright tends to be the exception and is more often vested in the creator, unless the work was commissioned by the university.

Applications to ABS

Universities in Canada could directly incorporate intellectual property aspects of national ABS policy into their institutional IP ownership policies. Inventive and commercial rights of indigenous communities, the Nation state and other appropriate entities would be explicitly recognized through contractual agreements with researchers and their sponsoring institutions, using existing (or modified versions of existing) contract templates.

Benefits would include building on institutional structures that are already in place (e.g., administrative assistance, contract templates, in-house legal and business expertise) and increasing the institutional awareness of the complexity in researcher/institutional/Nation state/indigenous rights issues in research involving genetic resources and traditional knowledge. A significant challenge would include dealing with the diversity in IP ownership policies across Canadian institutions. For example, institutions that require a transfer of ownership rights from inventor to institution as a pre-requisite to intellectual property protection, licensing, and commercialization may not provide a flexible enough negotiating environment to accommodate the interests of all stakeholders, particularly when the traditional knowledge of indigenous peoples is involved. In fact, this situation raises a potential conflict between researchers' obligations to indigenous participants in research under national human research ethics policy and researchers' obligations to their sponsoring institutions under their institutional IP ownership policies.[10] The mandate of many university technology transfer offices includes education of researchers through seminars, printed and electronic information materials, and meetings, so educative outreach opportunities to discuss ABS policies and issues more broadly with university scientists also exist.

Extra-institutional Codes of Ethics and Research Guidelines

Existing structures

In addition to their institutional research ethics requirements, many scientists are obliged through voluntary membership to abide by the ethical research standards of national or international professional associations and academic societies. Professional associations (e.g., medicine, engineering, law, education) have enforceable mechanisms for disciplinary action against members while academic societies (e.g., anthropology, archaeology, sociology, ethnobiology, pharmacognosy, chemistry, biology) take a more educative approach to ethical research practices, largely relying on compliance through peer pressure and individuals' concerns about their own reputations. Some societies use formal Codes of Ethics to articulate their ethical standards,[11] while others use guidelines, position papers, or resolutions to set out expectations for their members.[12] Most of these ethical standards are considered "living documents", thus are subject to periodic revision as ethical and legal considerations in research evolve.

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[10] For further discussion see Bannister (in press).

[11] Ethical standards specified in *Codes of Ethics* include those of the American Anthropological Association (http://www.aaanet.org/committees/ethics/ethics.htm), International Society for Ethnobiology (http://guallart.anthro.uga.edu/ISE/soceth.html), Society for Economic Botany (http://www.econbot.org/ethics/), Society for Conservation Biology (www.conbio.org/2004/MembersMeeting/Ethics_Statement_2004_07.pdf), Society for Environmental Toxicology and Chemistry (http://www.setac.org/htdocs/who_code.html), American Institute of Chemists (http://www.theaic.org/DesktopDefault.aspx?tabid=46), and American Chemical Society (http://www.chemistry.org/portal/a/c/s/1/acsdisplay.html?DOC=membership\conduct.html).

[12] For example, the American Society for Pharmacognosy has adopted membership *Guidelines for Interactions with Source Countries* (see Journal of Natural Products 1997, 60, 654-655), which consider issues related to consent, compensation, conservation, and the rights of Indigenous communities. A technical report on medicinal chemistry prepared by the International Union of Pure and Applied Chemistry (http://www.iupac.org/reports/1996/6812andrews/index.html) considers issues such as access, benefit-sharing and intellectual property rights in relation to use of biodiversity for natural products development. Position statements of the American Folklore Society on ethics and human subjects (http://www.afsnet.org/aboutAFS/ethics.cfm) outline specific responsibilities to protect the welfare of participants in ethnographic research. The International Chemical Society has adopted conservation and reciprocity-based principles embodied in its *Göteborg Resolution* (http://www.chemecol.org/society/about.htm).

Applications to ABS

Relevant professional associations and academic societies could be strongly encouraged to incorporate the underlying principles of ABS policy into the ethical requirements for their members. Given the significant uncertainty that unresolved ethical and legal issues have created for research involving genetic resources and traditional knowledge, more explicit guidance on some of these through ABS policy would likely by welcomed by most organizations.

Benefits of targeting associations and societies would include high visibility and educative opportunities for generating awareness of ABS issues, and the ability to reach individuals who fall outside the institutional structures discussed previously.

Community Protocols

A relatively new phenomenon in Canada and some other countries (e.g., Australia) is the emergence of local research protocols developed by indigenous groups or research organizations that work closely with such groups. These protocols tend to specify local expectations and conditions for research, based on a combination of customary laws and traditional practices, as well as practical realities of contemporary life. Community protocols are increasingly being used to define relationships between indigenous communities and outside researchers.[13] Assuming ABS policy was developed with appropriate participation of indigenous groups and collaborating research organizations (and therefore had their support in principle), these groups could be encouraged to incorporate ABS policy into their research protocols. This would thereby strengthen local-national policy links by generating further awareness and consistency in policies among users and providers of genetic resources.

ABS as a Catalyst for Integrated Policy Evolution

There is an obvious need for an over-arching national ABS policy that is tailored to Canadian needs and yet is consistent with an international ABS regime. The substance of such a policy has yet to be determined through appropriate national dialogue within Canada, but it will have to address ethical, legal and political dimensions of research involving genetic resources, especially when research also involves traditional knowledge.

This paper addresses one possible framework for the implementation of a national ABS policy, i.e., entrenching ABS policy into well-established university review processes that have built-in compliance mechanisms. This is proposed as a partial strategy to facilitate compliance by the academic research community, including university scientists, students and administrations. Beyond these institutional structures, ABS policy could, foreseeably, also be incorporated into the ethical standards of relevant professional and academic organizations, as well as local research protocols developed at the community level. Assuming the substance of a national ABS policy is developed collaboratively and with these diverse interests in mind (a formidable task), the academic research community and indigenous groups alike would likely welcome the increased certainty in expectations about ABS that such a standard would offer.

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[13] Some examples are the *Code of Ethics for Researchers Conducting Research Concerning the Ktunaxa Nation* (Canada), *the 'Namgis First Nation Guidelines for Visiting Researchers/Access to Information* (Canada), *Principles and Guidelines for Researchers Conducting Research With and/or Among Mi'kmaw People* developed by the Mi'kmaw Ethics Watch (Canada), *Guidelines for Respecting Cultural Knowledge* published by the Alaska Native Knowledge Network and adopted by the Assembly of Alaska Native Educators (Alaska), *Traditional Knowledge Research Guidelines* prepared by the Council of Yukon First Nations (Canada), and *Guidelines for Ethical Research in Indigenous Studies* developed by the Australian Institute of Aboriginal and Torres Strait Islander Studies (Australia).

There is an additional and significant advantage in bringing ABS policy into the proximity of university research policy. It would serve as a useful context for addressing potential conflicts between research ethics and IP ownership policies in commercially oriented research that involves both genetic resources and traditional knowledge. This could provide the necessary catalyst for a more integrated approach to co-evolution of university research ethics and IP ownership policies in Canada, encouraging research partnerships by leading to more uniformly ethical and equitable treatment of all interests in the research.

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Scientists as Users and Providers: A South African Perspective

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In South Africa, which is the third most biodiverse country in the world,[1] at least 80% of the 18 to 20,000 plant species are known to be endemic. Intra-specific genetic diversity is also unusually high, adding to the potential for developing new medicines, crops, cosmetics, ornamental plants and other useful products.

South Africa's Constitution (Act 108 of 1996) provides the central framework for the management of biodiversity in South Africa. The national and nine provincial governments are accorded concurrent legislative competence in terms of most of the functions which are of relevance to biodiversity, such as agriculture, environment, nature conservation, pollution control, regional planning and development, soil conservation, urban and rural development and tourism. Areas of exclusive national competence include national parks, botanical gardens and marine resources.

Genetic resources and their ownership are, however, not dealt with explicitly in the Constitution and there is still a need for legal clarity on this issue. According to Chishakwe and Young (1993), no country has yet found or developed a workable legal framework because of the difficulties of defining 'genetic resources' and the lack of legal understanding on the matter. Most of South Africa's biodiversity falls under private ownership and under South African law a landowner owns everything beneath and above the land, including plants but excluding wild animals which are considered to be *res nullius* (not owned by anyone). Most State and commercial agricultural land is held under freehold, while 13% of the country is under customary tenure. While statutory laws apply in both circumstances, in communal areas some customary law also applies and is central to the practice of natural resource use.

At the end of May 2004, the Biodiversity Act (No. 10 of 2004) was signed by the President. Chapter 6 of the Act is entitled 'Bioprospecting, Access and Benefit-Sharing' and sets out the framework for the regulation of access and benefit sharing (ABS) in South Africa. The purpose of this chapter is to:

- Regulate bioprospecting involving indigenous biological resources;
- Regulate the export from the Republic of South Africa of indigenous biological resources for the purposes of bioprospecting or any other kind of research, and
- To provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The indigenous biological resources referred to here also include derivatives, chemical compounds and products obtained through the use of biotechnology. Material of human origin is excluded as well as exotic organisms and the indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

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[1] World Conservation Monitoring Centre, 1992. *Development of a National Biodiversity Index: A discussion paper.*

Under the Act, permits are required for all bioprospecting projects and for the export of any indigenous biological resource to be used for bioprospecting or for any other kind of research. Stakeholders who provide access to resources or knowledge must be consulted and their prior informed consent obtained before a permit will be issued.

The Act distinguishes between the procedures to be implemented when obtaining indigenous biological resources, where a Material Transfer Agreement (MTA) is required between the applicant and 'stakeholder' as well as a benefit-sharing agreement before a permit will be issued, and those involved when accessing knowledge which require a benefit-sharing agreement; to be negotiated. Ministerial approval is required for both MTAs and for benefit-sharing agreements and a Biodiversity Trust Fund is established into which all moneys arising from bioprospecting projects must be paid.

Benefit-sharing agreements must indicate how the resources will be used, the type and quantity of resources to be collected, the area of collection, traditional uses of resources and potential uses and the extent to which the stakeholders will share in the benefits. MTAs must set out the particulars of the provider and recipient, the type and quantity of resources to be provided, the area of collection, the purpose of export, potential use and conditions for transfer to a third party. However, provisions requiring benefit-sharing agreements to be developed and approved by the Minister fail to recognize that full benefit-sharing agreements are usually only negotiated once the research and development has proceeded further although benefits such as information sharing, technology transfer and capacity development could be implemented immediately. Furthermore, the requirement for the Minister to approve both benefit-sharing agreements and MTAs may well result in further delays in acquiring access to biological resources. It is doubtful whether this level of bureaucracy is necessary for the approval of MTAs as these simply cover the exchange of material between parties with a proviso to prevent commercialization of the material unless a benefit-sharing agreement is negotiated.

The procedures relating to the issuing of permits, which are covered in Chapter 7, are not clear with most of the detail being left to be included in the regulations that have yet to be developed. This has resulted in an understandable reluctance on the part of provincial authorities to grant permits for anything other than research purposes until such time as there is greater clarity on this matter.

Other than for export purposes, research has been excluded from the law. However, because it is often difficult to distinguish between academic (basic) research and commercial research, this may result in many bioprospecting projects being excluded from the stipulated permitting and agreement requirements. The Government Gazette (Vol. 472 October 8, 2004) states that it is expected that Chapter 6 of the Act will only be implemented by January 2006, thus making provision both for the development of regulations to implement this chapter as well as the possible introduction of changes which will facilitate the process of access to biological resources and the implementation of benefit-sharing.

Despite the legal vacuum which existed in South Africa before the passing of the Act, a number of research organizations have developed policies on access and benefit-sharing. The Council for Scientific and Industrial Research (CSIR) developed their policy in 1999, which stipulates that they will act in accordance with the Convention on Biological Diversity and all national legislations. The policy does not refer to the necessity to obtain prior informed consent, but states that the CSIR will only undertake bioprospecting research when the provision for fair and equitable sharing of benefits has been made.

The National Botanical Institute, which with the passing of the Biodiversity Act has been converted into the South African National Biodiversity Institute, has developed an ABS policy based on the

Common Policy Guidelines for Botanic Gardens (Garcia F. L. et al. 2001). This policy recognizes the need to obtain prior informed consent and undertakes to acquire and supply genetic resources, their progeny or derivatives under MTA agreements. A commitment is also made for the fair and equitable sharing of benefits with relevant stakeholders.

The provincial authorities in the nine different provinces of South Africa, are at various stages in the development of policies. Ezemvelo Kwa-Zulu Natal Wildlife was the first conservation agency in South Africa to have a bioprospecting policy which was adopted in 2000 and which recognizes that traditional communities have the right to control their land and resources and secure benefits from the use of their knowledge. All research is required to contribute to conservation and development in areas in which it takes place. Only requests to collect from protected areas from *bona fide* South African Research Institutions will be considered until the national and provincial legislation is in place (Wynberg, R. 2004).

In addition to the development of specific policies, there have also been attempts to develop a code of ethics and set of research guidelines for researchers working with South African biodiversity and local communities, through the Indigenous Plant Use Forum. This is a local networking organization for researchers working on indigenous plants in SA. The code of ethics and guidelines, based on those adopted by the International Society of Ethnobiology and the Pew Conservation Scholars Initiative have been adapted to meet local requirements. The aim is to broaden the acceptance of the code by.a wide range of organizations and researchers but it has been found to be rather challenging to engage some researchers on this matter and persuade them about the relevance of these issues to their work (Wynberg, R. 2004).

Within government and many other institutions at national level and other levels, expertise on ABS is deficient, particularly in the areas of contract negotiating skills, legal drafting skills and technical skills to enhance biodiversity assessment work and increase understanding as to the commercial pathways of natural product development. Officials also require training to enforce and implement laws.

Despite the fact that there is substantial scientific and technical expertise in SA, there are deficiencies with regard to the assessment, inventory and monitoring of genetic resources, the valuation of genetic resources, the development of information systems at national and regional levels to enable improved coordination and understanding and awareness with respect to benefit-sharing, and the protection and recognition of traditional knowledge about biodiversity. Improved legal understanding is also required, more specifically in terms of ownership of genetic resources and protection of traditional knowledge and farmer's rights. Although much emphasis has been placed on the "discovery phase", more specifically screening techniques, DNA sequencing and characterization, marketing and product development are critical gaps because they have implications for the extent to which value can be added to local biodiversity products.

In the past few years, several research consortia have been established in SA to integrate the disciplines of microbiology, chemistry, pharmacology and ethnobotany. Not only have the technical competencies of these disciplines been complimented through this process but also that of a number of different research councils, universities and institutes. This has been accompanied by the initiation of a number of bioprospecting projects involving consortium members and foreign organizations. The focus of the national bioprospecting consortiums is on the discovery of drugs from indigenous plants in order to make a unique contribution to the search for novel drugs in southern Africa. Key partner organizations include the CSIR, Medical Research Council, South African National Biodiversity Institute, the Agricultural Research Council and several universities.

Funding was provided by the National Research Foundation's Innovation Fund for a major project focussed on the identification and development of anti-malaria drugs. The consortium owns a database containing records of 700 plants, all of which it has been claimed have been used in the treatment or prevention of malaria. The main objective of the project is to develop new medicines based on indigenous plants and indigenous knowledge for the treatment of malaria. The project also aims to create multi-disciplinary scientific capability to derive anti-malarial drugs, create jobs through cultivation and agroprocessing, develop a technology platform for South Africa comprising all the elements of the "value chain" for drug discovery and to create economic benefits for SA through product innovation and royalty earnings. A Trust Agreement has been set up between the members of the consortium in which it has been agreed that any financial benefits generated as a result of the project are to be divided in half, with 50% of the benefits being shared equally by the partners and the remaining 50% being deposited into a Trust Fund to be shared with the stakeholders who have contributed to the project.

Some years ago, scientists at South Africa's CSIR isolated a chemical entity extracted from *Hoodia gordonia* called P57 that suppresses appetite, and this was patented in 1996. Phytopharm plc, a listed British company was licensed in 1997 by the CSIR to undertake the further development and commercialization of the patented discovery. In 1998, Phytopharm signed a licensing agreement with the US pharmaceutical giant, Pfizer Inc., for the development and global commercialization of P57. Pfizer informed Phytopharm in mid-2003 that it would be discontinuing the clinical development of P57 as a result of the closure of the Natureceutical group, and returned the licensing rights to Phytopharm.[2] Phytopharm is presently negotiating with another company to undertake the clinical development of P57.

In July 2001, while describing the research progress of P57, a spokesman for the project that linked the San people with *Hoodia* implied that the tribe had in fact died out. An international outcry followed, resulting in the setting up of the South African San Council in November 2001, who then threatened a lawsuit on the project. Negotiations with the CSIR followed and the San Council demanded recognition of their knowledge and a share of the benefits. An Agreement with the San, who have a long history in Southern Africa and who have used *Hoodia* to suppress hunger and thirst during their hunting trips in the Kalahari, was signed in March 2003.

Under this agreement the CSIR will pay the San 8% of the milestone payments made by its licensee, Phytopharm, during the drug's clinical development over the next three to four years and will make study bursaries and scholarships available to the San community. The San could earn 6% of all royalties if, and when, the drug is marketed, possibly in 2008. Milestone payments for the San could reach between US$1.2 million to US$1.8 million while the royalties could top US$9.4 million annually during the 15 to 20 years before the patent expires.

However, the process is further complicated because the indigenous knowledge related to this resource is also held by communities across national borders, in this case, South Africa, Namibia, Botswana, and Angola (Geingos, V. & Ngakaeaja, M., 2002). Consequently, any income generated will go into the San Hoodia Benefit Trust set up by the CSIR and the San. The beneficiaries will be the San people of South Africa and San communities elsewhere who are members of the Working Group of Indigenous Minorities in Southern Africa (WIMSA) and who are identified by the Trustees as eligible beneficiaries. The Trust includes representatives of the CSIR, the regional San councils, WIMSA and an observer from the South African Department of Science and Technology (Terblanche, P., 2003).

Species of biological resources also do not recognize political boundaries and often occur in several countries. Consequently, the Organization of African Unity Council of Ministers recommended that African countries develop national legislation as well as regional regimes dealing with the exchange of biodiversity, knowledge, innovations and practices, and the African Model Law was developed with the objective of guiding this process.

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[2] Phytopharm Annual Report, 2003.

The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources aims to protect Africa's biological diversity and livelihood systems with a common tool (Ekpere, J.A., 2001). The development of the African Model Law was the result of a number of initiatives from the Scientific, Technical and Research Commission of the OAU, the Ethiopian Environmental Protection Authority and the Institute for Sustainable Development in Ethiopia. However, the social and political realities vary across different African countries and flexibility is required to adapt the African Model Law to the priorities and needs of each African nation.

The SANBI is the South African partner in the Millennium Seedbank Project with Kew Royal Botanic Gardens. The project is an international collaborative plant conservation initiative, which aims to safeguard 24,000 species from around the world against extinction. The major focus of the South African project is the collection of threatened and endemic species. The relationship between Kew and SANBI is governed by a legally binding Memorandum of Understanding which deals with joint collecting activities, exchange of material and transfer, benefit-sharing and ownership of the material, its progeny and derivatives, which remains vested in the South African Government. Repatriation of material, the prohibition of commercialization and the transfer of material to third parties which requires the supplier's permission and confidentiality of information are also covered in the agreement.

The Darwin Initiative Project, entitled 'DNA Banking, Phylogeny and Conservation of the South African Flora 2003- 2006', and funded by the UK Department for Environment, Food and Rural Affairs (DEFRA), has resulted in the setting up of a DNA Bank at the SANBI Kirstenbosch Research Centre, along with the establishment of technology training, research and educational programs, in collaboration with Kew. The project aims to archive genetic material from at least one species of all the 2,200 South African flowering plant genera. Researchers will be allowed to access plant DNA extracts to produce a phylogenetic 'tree of life'. The Memorandum of Agreement governing the establishment and operation of the DNA Bank also deals with issues such as exchange of material between Kew and SANBI, access to that material and the sharing of information and data. Issues such as non-commercialization, the requirement for separate benefit-sharing agreements in the event of commercialization, ownership of the material which remains vested in the South Africa government and transfer to third parties is also dealt with under the Agreement.

SANBI is responsible for the management and execution of the South African component of the Southern African Biodiversity Support Programme, a GEF funded project being carried out in 10 Southern African countries. To assist in the implementation of the ABS component of this project, a questionnaire was designed to provide an overall assessment of the use of biological resources in South Africa, the processes and procedures in place to access these biological resources and indigenous knowledge, and the existing benefit-sharing mechanisms.

The questionnaire was sent out to a selection of stakeholders involved in the utilization of biological resources in national and provincial government departments, pharmaceutical companies, academic institutions, industry, traditional healers, NGOs and community-based organizations. Some of the issues covered by the questionnaire included whether the stakeholders entered into any agreements before supplying or acquiring biological resources and indication whether there was any form of benefit sharing mechanism put in place. Stakeholders were also requested to list all the difficulties experienced and lessons learnt when supplying or acquiring biological resources and gaining access to traditional knowledge.

An analysis of the responses to the questionnaire indicated that, in most cases, stakeholders first applied for permits to collect resources. Agreements, in the form of Material Transfer Agreements, contracts, or Memoranda of Understanding (MOU) were signed before the permits were issued and the collections took place. Stakeholders who collected biological resources for academic research and those in the communities frequently did not participate in the drawing up of agreements or equivalent MOUs. Some of the stakeholders in academic institutions explained that this was mainly because collections were carried out primarily for research purposes and there was no intention to commercialize the outcomes of the research.

About 50% of the suppliers of biological resources reported that no benefit-sharing mechanism existed between them and collectors. In some instances, this was because the collections are carried out without any requests for benefits in return for the supply of biological resources. The other 50%, however, indicated that benefits had been identified and ranged from immediate cash, fees per sample collected, to copies of information, reports and data. Some stakeholders reported that difficulties were experienced because the perception existed that the aim of researchers was to make money from the specimens collected and that they were collaborating with foreign companies who had come to Africa to "steal" natural resources. Thus, there was a reluctance to supply information and material. Another major problem was the lack of trust existing between suppliers and collectors.

A difficulty identified by many stakeholders was that the present procedure to obtain permits was often disorganized and not applied consistently throughout all the provinces. In terms of benefit-sharing, stakeholders felt that once the words benefit-sharing were mentioned, most of those requesting material became disinterested and negotiations tended to end at that point.

Research is a crucial basis for both the conservation and sustainable use of biological resources and any International Regime which is negotiated should contribute to the facilitation of access to resources in a controlled manner that ensures the fair and equitable sharing of benefits.

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DISCUSSION PAPER

Relevance of Genetic Resources to the Pharmaceutical Industry[1]

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Introduction

For most of the developing world, it may be an understatement to note that intellectual property (IP) protection is viewed with trepidation and suspicion. Despite the documented developmental benefits of IP,[2] it has become a source of debate and polarization in multilateral fora, including the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Council, and the Convention on Biological Diversity (CBD).[3,4] With the widely-held perception within the developing world that WIPO and WTO discussions tilt towards the interests of Western, more developed economies (such as the U.S. and Europe), developing countries increased their presence and engagement in biodiversity-related issues which culminated in the negotiations that established the CBD in 1992.

If WIPO and the TRIPS Agreement within the WTO are viewed by anti-IP activists as primarily benefiting the developed world, the CBD was intended to be a direct counter-point that would ensure that developing countries and their indigenous peoples retained sovereignty and control over natural resources and related bio-diversity found in greater concentration in developing countries.[5] Concerns about the negative tone of countries on intellectual property protection, expressed primarily by key developing countries during the negotiations, contributed to the U.S. decision to defer ratification of the CBD,[6] notwithstanding that most European and other WIPO/WTO members had adopted and implemented the CBD.[7]

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[1] Susan Kling Finston, with research assistance from Paul Hanna, MPP, University of Michigan Ford School of Public Policy (expected Spring 2005). This article is based on a presentation initially made at the International Society of Environmental Biotechnology, Seventh Biennial Symposium, June 21, 2004, in Chicago, IL. A draft of this paper was subsequently presented at the 5th Princess Chulabhorn International Science Congress: Evolving Genetics and its Global Impact, August 17, 2004, in Bangkok, Thailand.

[2] Zavin, Jonathan, et al. 1997. *The Value of Intellectual Property Rights Enforcement in Developing Countries. Economic Perspectives*. June 1997. [http://usinfo.state.gov/journals/ites/0697/ijee/ej7com1.htm]. Taking the real-world case of Mexico. Since the adoption of strong intellectual property for medicines, Mexico has eradicated Smallpox and Polio; developed "State of the Art" vaccines, like those to prevent meningitis, gastrointestinal and respiratory infections, and increased average life expectancy increased in Mexico from 52 to 74 years, including a reduction by more than 50% in the rate of early childhood mortality. See the 2004 Annual Report, *Association Mexicana de Industrias de Investigacion Farmaceutica* (AMIIF). See also George G. Korenko, 1999. *Intellectual Property Protection and Industrial Growth, A Case Study*, The Journal of World Intellectual Property, January 1999, No. 1, pp 47 – 75, which found that patent protection transformed the pharmaceutical industry into one of Italy's leading industries, with annual average growth of more than 5.4% at a time when average GDP growth overall was only about 1.5%. For more recent data on benefits of intellectual property for middle-level developing countries, see, Ryan, M P. and Shanebrook, J., 2004. *Establishing Globally-Competitive Pharmaceutical and Bio-Medical Technology Industries in Jordan: An Assessment of Business Strategies and the Enabling Environment*, International Intellectual Property Institute and the AMIR Project, August 2004.

[3] *Brazil rejects proposal for global patent. Gazeta Mercantil Online (Brazil)*. Oct 2, 2002.

[4] Hirano, Ko., 2003. *U.S., Poor Nations remain apart over WTO drugs row. Japan Economic Newswire*. Feb 15, 2003.

[5] *Convention on Biological Diversity*. Article 3. June 5, 1992. (http://www.biodiv.org/convention/articles.asp)

Most recently, at the Seventh Conference of the Parties (COP-7) of the CBD, Ministers agreed to undertake the most ambitious and possibly the most far-reaching negotiations in the history of the Convention. These negotiations will deal with the issue known as Access and Benefit-sharing (ABS) relating to "genetic resources" (all non-human, i.e. plant, animal or microbial materials). While far from definitive, the COP-7 Ministerial Declaration left open the possibility of the establishment of a mandatory international ABS regime that would have a chilling effect on patent rights for biotechnology-inventions. This Declaration demonstrates the continuing ambivalence of much of the world's governments to the ability of current IP protection systems to meet their developmental needs, and the corresponding fear that developed states are using IP in an unfair way to take advantage of the so-called "mega-diversity" in the developing world without providing commensurate benefits.

On a regular basis, the media reports allegations of "bio-piracy," e.g. assertions that Western scientists have appropriated biological specimens without adequate compensation for developing countries or their indigenous peoples. These assertions resonate with the public, but unfortunately create a misleading and incorrect impression about the prevalence of this activity. More troubling, this implies that most corporations and scientists fail to comply with CBD-based rules, such as prior informed consent and benefit-sharing. As a rule, while U.S. and European corporations follow current voluntary CBD ABS guidelines, the increasing intensity of the focus on ABS issues has had the overall effect of reducing interest in natural products as a source for the research and development activities of multi-national corporations.

What this means is that, despite the potential that may exist in natural products that could yield benefits for consumers and patients around the world, the increasingly negative focus on ABS by developing countries is driving down interest among the commercial sector to evaluate natural products for potential R&D efforts. This has resulted in a decreasing level of activity in this field by the biotech and pharmaceutical industries. International research-based bio-pharmaceutical companies have largely downsized R&D efforts focused on natural products, preferring instead to advance work in synthetic drug development. Despite the efforts of many developing countries to establish bio-technology hubs as a focal point for development in the 21st century, the absence of predictable and transparent ownership for biodiversity-related natural resources has led to a dearth of investment in biotechnology outside of the U.S., with even European markets falling short of predicted investment.[8] This is an unfortunate situation for all concerned: patients around the world, indigenous populations in developing countries and the international research based bio-pharmaceuticals industry.[9]

Twenty-five years ago, the U.S. faced a similar situation, in which the U.S. Government had invested heavily in biotechnology research, only to see industry fail to commercialize with few resultant benefits for US taxpayers. In the late 1970's, the U.S. failed to provide clear and exclusive rights in biotechnology inventions for scientists and corporations. Through a series of legislative initiatives, the U.S. established new forms of public-private rights-sharing agreements that revolutionized biotechnology in the U.S. and the rest of world. The U.S. experience of twenty-five years ago is especially relevant for CBD members, who are about to embark on an open-ended negotiation to establish a framework for internationally binding commitments in genetic resources relating to biotechnology inventions - which could raise even more questions about the future viability of natural products R&D. It is critical, at this point before the ABS negotiations begin, to get the questions right before settling on pre-determined answers. The well-being of patients and future prospects for biotechnology in developing countries depend on those questions.

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[6] Coughlin Jr., M. D., 1993. *Using the Merck-INBio Agreement to clarify the Convention on Biological Diversity*. Columbia Journal of Transnational Law. 31 (2): 337-75 (1993).

[7] As of May 25, 2004, there are 188 parties to the CBD and 168 signatories (http://www.biodiv.org/world/parties.asp)

[8] Griffith, Victoria, 2003. *Biotech reaches a turning point in its evolution*. Financial Times 17 December 2003: 16.

[9] For an early discussion of the risks of increased politicization of genetic resources for commercialization of natural products research, please see: *Biotechnology, Globalization and Intellectual Property*, WIPO Industry Advisory Commission (Third Session, May 4 and 5, 2000), Attachment VII DOC.B. This presentation presaged many of the developments outlined in this paper.

Developing Country Interest in Access and Benefit-sharing (ABS) within the CBD

Developing countries came together at the 1992 United Nations Conference on Environment and Development, also known as the Rio Earth Summit 1992, to form the Convention on Biodiversity (CBD) and in large part to act as a counterweight to the binding intellectual property (TRIPS) obligations that were then being negotiated within the WTO. Unlike the WTO, which was perceived by some as providing disproportionate benefits to the West, the CBD declared the sovereignty of the developing world and their indigenous peoples over their bio-diverse resources, based on an assumption that developing countries environments provide unique benefits for natural products R&D.

The stated objectives of the CBD were:

- The conservation of biological diversity;[10]
- The sustainable use of biological diversity,[11] and
- The fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including access to these resources and the transfer of relevant technologies.[12]

The latter objective focused on an ill-defined but critical commitment to ensure that benefits from the commercial development of new products related to bio-diverse resources would also flow back to developing countries. This became known as Access and Benefit-sharing, or ABS.
Developing countries have continued to demonstrate a serious commitment to formulating systems for ABS both within the CBD and in the WTO and WIPO.[13] The ABS goals of these countries have been articulated in multiple fora, including the group of 12 Like-Minded Megadiverse Countries, the WIPO Patent Cooperation Treaty and Substantive Patent Law Treaty talks, and in numerous submissions to the TRIPS Council.[14,15]

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[10] Convention on Biological Diversity, Article 15 (June 1992), accessed at: http://www.biodiv.org/convention/articles.asp

[11] Ibid.

[12] Ibid.

[13] For discussion of the early involvement of WIPO in the debate over binding legal obligations relating to genetic resources, see Intellectual Property and Genetic Resources – An Overview, WIPO/IP/GR/00/2, March 24, 2000; demands by developing countries for a binding regime under the authority of WIPO have been made repeatedly in the intervening years (Committee's Fifth Session, WIPO/GRTKF/IC/5/15, paragraphs 16, 22, 80 and 126, as well as WO/GA/30/8, Report of the WIPO General Assembly, paragraph 65 to 92, passim).

[14] See, *Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru Thailand, and Venezuela for the TRIPS Council meetings*, IP/C/W/403. 24 June, 2003.

[15] Joint communication from the African Group for the TRIPS Council meeting. IP/C/W/404. 26 June, 2003.

The Cancun Declaration of Like-Minded Megadiverse Countries is illustrative of these objectives:

> [We] seek the creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components. **This regime should contemplate, inter alia, the following elements: the certification of the legal provenance of biological materials, prior informed consent and mutually agreed terms for the transfer of genetic material, requirements for the application and granting of patents,** strictly in accordance with the conditions of access agreed by the countries of origin.[16] [emphasis added]

The Cancun Declaration added fuel to the concerns of bio-pharmaceutical companies that CBD members seek to encumber patent rights for biotechnology. Implicit in the foregoing, as well as in the structure and formation of the CBD, is the developing country fear of illegitimate "bio-prospecting" – the idea that pharmaceutical companies will harvest natural material from the developing world and reap great profits from these materials without reimbursing the host country or its indigenous populations. This fear is misplaced, given that the likelihood of a blockbuster product originating from a discovery in a rain forest or jungle is much more remote than conventional wisdom would suggest.[17] And, more importantly, the examples of "bio-piracy" frequently cited by activist groups rest on a shaky factual foundation.

New voluntary principles associated with ABS were codified in the Bonn Guidelines, adopted formally by CBD members in April, 2002, closely tracking a number of the goals outlined in the Cancun Declaration. The main provisions of the Bonn Guidelines are:

- *Prior Informed Consent (PIC)*: Private or public enterprises seeking to acquire biological material should attain consent from the country within which the material resides prior to collection;
- *Certification of Origin/Legal Provenance*: A certificate from the provider of genetic material, whether it be a university, ministry, or other organization, that notes the origin of the material and can be used to track the material;
- *Disclosure*: Countries may consider measures to encourage disclosure of origin of biological materials or traditional knowledge in patent applications;
- *Technology Transfer*: As stated in the CBD, the "appropriate transfer of relevant technologies" used in the collection and/or study of genetic material;[18]
- *Benefit Sharing*: As required by the CBD, "fair and equitable sharing of the benefits arising out of the utilization of genetic resources";[19] and
- *National Focal Point*: Each CBD Members may designate one national focal point to inform applicants for access to genetic resources on how to follow PIC and Benefit-sharing guidelines, as well as informing the applicant of relevant indigenous and local community stakeholders.

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[16] Cancun Declaration of Like-Minded Megadiverse Countries. 18 Feb. 2002. [http://www.unido.org/file-storage/download/?file_id=11803]

[17] Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting. Nature* V. 392 (1998): 535-540.

[18] *Convention on Biological Diversity*. June 5, 1992. (http://www.biodiv.org/convention/articles.asp)

[19] Ibid.

The Bonn Guidelines outline considerations that CBD members should consider in the formulation of national ABS regimes, as called for in the CBD. The CBD Secretariat has recently reported that very few CBD members have implemented integrated and effective ABS regimes at the national level.[20] Now that the COP-7 has called for the negotiation of a broader International Regime (IR) for ABS, some CBD members have expressed concern that planned negotiation of a comprehensive IR may remove any incentive for the timely and appropriate implementation of the Bonn Guidelines, and may further delay the implementation of appropriate ABS measures at the national level.

Missing in the CBD debates is a clear understanding of the important and positive role of intellectual property protection to support and encourage investment by private companies, which is essential for the successful commercialization of natural products derived from genetic resources. The technology transfer in biotechnology that is specifically called for in the CBD necessitates substantial long-term investment by industry. Private sector investment on this scale, however, is only possible with clear exclusivity periods, like those provided by patents. As David Schwartzman points out: *"without patents the return from investment in pharmaceutical research and development would fall to zero, and private companies would no longer engage in research and development"*.[21] The case of penicillin provides an instructive lesson of how development is delayed in the absence of patents. Penicillin was first discovered in 1928, yet no patent on penicillin or its manufacture was taken out until 1948. As a result, penicillin remained wholly unutilized until WWII, where the mass casualties due to infection necessitated large scale manufacturing of the drug.[22]

As a result of growing antipathy toward patent rights within the natural products community, and due to global competition for foreign direct investment associated with drug discovery, international research-based pharmaceutical companies have drastically reduced their natural products or even eliminated them.[23] Merck and Lilly, for example, have both cut programs for collecting samples and isolating extracts from natural biological sources.[24] David Newman, a senior chemist working at the natural products branch of the National Cancer Institute, is not surprised by this development, stating that "Industry is not doing that much [with natural products], compared with what it used to do". He estimates that natural drug discovery faces extremely long odds, calculating that only one sample in 250,000 will eventually yield a commercial drug, although many more samples may provide leads for other drugs.[25] At the same time, combinatorial chemistry blossomed during the 1990's as the preferred method of creating and examining new molecules. It was cheaper, faster, and provided more clarity with respect to intellectual property rights than natural product development.[26] Today, 5000 assays can be done at a time using thousands of slightly different molecules.

Improvements in chemical synthesis, occurring against a backdrop of hostility toward patent protection and commercial enterprises relating to natural product development in general, has led to the questioning of the need for natural products R&D altogether. David Galas, president of

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[20] *National Implementation* paper presented by Valerie Norman, Programme Officer, Access and Benefit-sharing, Convention on Biological Diversity Secretariat, at the ABS International Expert Workshop on Access to Genetic Resources and Benefit-sharing, Cuernavaca, Mexico, October 25, 2004.

[21] Schwartzman, D., 1976. *Innovation in the Pharmaceutical Industry.* Baltimore: Johns Hopkins Press, 1976.

[22] Public Broadcasting Service: *A Science Odyssey: People and Discoveries.* (http://www.pbs.org/wgbh/aso/databank/entries/dm28pe.html)

[23] Rouhi, A. M., 2003. *Betting on Natural Products for Cures. CENEAR,* 81 41 (2003): 93-103. [http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html]

[24] Ibid, see also Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting. Nature* V. 392 (1998): 535-540.

[25] Ibid.

[26] Rouhi, A. M., 2003. *Rediscovering Natural Products. CENEAR,* 81 41 (2003): 77-91. [http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals.html]

Darwin Molecular, a biotechnology company, believes that natural products are now left "completely high and dry". He goes on to say that "the idea of exploiting the rain forest to find wonderful drugs is, quite frankly, not credible".[27] However, others believe that the science merits further R&D. R. Murray Tait, Cerylid's Vice President for drug discovery, says "It's a shame that many of the big pharma companies got out of natural products just when technology was so dramatically improving the process".[28] As scientists argue both sides of the debate between combinatorial chemistry and natural products, private corporations are left trying to balance risks and costs, particularly those associated with developing country ABS regimes. If the risks and potential benefits were brought back into balance, at least some of these companies would have an incentive to venture back into natural product exploration.

Despite the CBD's ambiguities with respect to intellectual property, most major corporations in the US and Europe continue to meet the obligations laid out by developing countries. In fact, even before the CBD, pharmaceutical companies voluntarily entered into benefit-sharing agreements with developing nations in the early years of commercial biotechnology. Some of these pre-CBD partnerships between developing countries and public-private institutions led to positive benefit-sharing among all parties involved. The Merck/INBio agreement in 1991 is a case in point. The National Biodiversity Institute (INBio) of Costa Rica provided Merck with plant, animal, and soil samples in exchange for short-term, exclusive rights to study the samples as well as proprietary rights for any innovative product created from the INBio samples. In return, the company agreed to pay the Government of Costa Rica US$1 million and a percentage of the royalties obtained from any innovative products derived from INBio resources. Merck also provided INBio with relevant laboratory equipment. The Government of Costa Rica committed to using the proceeds from royalties toward conservation of biological diversity. This agreement illustrates the benefits of a non-statutory, contract-based approach to ABS. Clear patent rights and access to genetic material were provided to Merck, while Costa Rica benefited from investments of cash and technological equipment, with money earmarked for conservation. Such an agreement could fulfill the major objectives that developing countries later included in the CBD.

Another example of an early benefit-sharing arrangement was the agreement between the State Government of Sarawak and Medichem Research, which established Medichem-Sarawak Pharmaceuticals as a joint venture company. A Cooperative Research and Development Agreement (CRADA), which enumerated the benefits including royalties, technology transfer, training and participation in scientific and biotechnology research, was established.[29]

The case of Pfizer, Phytopharm, the South African Council for Scientific and Industrial Research (CSIR), and the San people of South Africa concerning the Hoodia plant, known as P57, is often cited, erroneously, as a case of inequitable benefit-sharing with respect to biological material and traditional knowledge. In fact, Pfizer had no relationship with the San people, and had no knowledge of the rights of the San tribe at the time that it entered into its contractual relationship with Phytopharm. P57 was originally patented by the CSIR. In 1997, Phytopharm, a British biotech company, engaged in a licensing agreement with CSIR to further develop and commercialize P57. In 1998, Pfizer licensed P57 from Phytopharm to develop it into a commercial product. However, the San people had been using the Hoodia plant for its appetite suppressing qualities for hundreds of years, and it was their use that led CSIR researchers to the Hoodia plant. CSIR filed the patent without informing the San tribe. When Pfizer acquired the license for P57 from Phytopharm, they had no contact with the San and actually were led to believe that the San tribe had died out. It was not until the San brought a case against the CSIR that they were recognized as an existing tribe. A benefit-sharing program has now been worked out between the CSIR and the San people, in which the San will receive a percentage of royalties Phytopharm receives on the commercial sales of pharmaceuticals containing P57.[30] Given this uncertainty, the potential users of bio-diverse resources may benefit from dealing with a national focal point, as called for in the Bonn Guidelines that provide meaningful assurances as to potential stakeholders.

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[27] Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting. Nature* V. 392 (1998): 535-540.

[28] Rouhi, A. M., 2003. *Betting on Natural Products for Cures. CENEAR*, 81 41 (2003): 93-103. [http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html]

[29] ten Kate, K. & Wells, A. 1998. *The access and benefit-sharing policies of the United States National Cancer Institute: A comparative account of the discovery and development of the drugs Calanolide and Topotecan.* Executive Secretary of the Convention on Biological Diversity. 1998. (www.biodiv.org/doc/case-studies/abs/cs-abs-nci.pdf)

The adverse experiences of companies like Pfizer and increasing bureaucratization of ABS obligations in developing countries both have contributed to the reduction in investment in natural products. Ironically, while it has led to reduced technology transfer and investment, the expanding universe of ABS guidelines within the CBD "has done little to quell poor nation's fears of exploitation".[31] As described above, the CBD has fundamentally failed in its primary objective, as it has not provided an effective framework for public-private partnerships. Rather, it has actively precluded "the anticipated bioprospecting bonanza".[32]

Given the current environment, it may be helpful to look for new models for global biotechnology development, and to review how the U.S turned around a similar challenge and developed its current biotechnology IP regime, which is credited with the launch of the biotechnology revolution. It is particularly important at this time to seek a new model, given the imminent launch of new ABS negotiations aimed at establishment of international obligations in the CBD.

The U.S. Experience

Nearly 25 years ago, the U.S. faced a similar challenge to that encountered currently in the CBD-ABS negotiations. In the 1960's and 1970's, there was a major concern in the United States that, despite increased funding for basic research by the U.S. Government, industry was adopting very few of the new technologies for commercial development of new products.[33]

In 1980, fewer than 5% of the 28,000 patents for which the U.S. Government held title were developed into commercial products by industry.[34] Companies faced a difficult and time-consuming process when they tried to obtain exclusive rights to U.S. Government inventions.[35] U.S. law only provided for the granting of non-exclusive rights, but this failed to encourage companies to invest in the application and development of new products. In short, "taxpayers were supporting the federal research enterprise, [but] they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products."[36]

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[30] Bio e-News. 2003. *The CSIR and San sign benefit-sharing agreement in the Kalahari*. March 2003. (www.csir.co.za/biochemtek/newsletter/mar/benefit_sharing.html)

[31] Dalton, R. 2004. *Bioprospects less than golden*. *Nature*, V. 429 (2004): 598-600.

[32] Ibid.

[33] The Bayh-Dole Act: A Guide to the Law and Implementing Regulation. Council on Government Relations (COGR), 1999, (http://www.ucop.edu/ott/bayh.html)

[34] Ibid, citing the U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-Dole Act by Research Universities," May 7, 1998.

[35] "[B]y the late 1970s there was a growing dissatisfaction with federal policies on patenting the scientific knowledge resulting from the research. Many government officials, for example, believed that federal laboratories were keeping information away from those who could make use of it. There was also a concern that because the government had retained title to inventions, no one was bothering to advance the research. There was no incentive to do so. Further, with the maze of bureaucracy caused by lack of a uniform policy, made companies reluctant to deal with the government, even if they were interested in the research." Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference - Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001 [http://www.bio.org/news/041101.html]. See also: *Innovation's golden goose*, The Economist, December 12, 2002, noting that "inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profits institutions sat in warehouses gathering dust."

The resultant legislation, known as the Bayh-Dole Act of 1980, together with other related legislation, enabled universities and research institutes to engage in the commercialization process by owning inventions and to work with industry to bring products to market. Bayh-Dole allowed for the exclusive licensing of inventions, with regulations that ensured that products were developed diligently and for the public good. University-industry partnerships allowed researchers to participate in the development of a product or process, speeding up commercialization.[37] Under Bayh-Dole, the inventor, the university and the industry all shared in the royalties resulting from the invention. Income derived by the university went back to fund additional research. The U.S. Government also benefited broadly by seeing scientific advances translated into products that benefited U.S. taxpayers. The Economist magazine notes that, as a result of the Bayh-Dole Act, America experienced "a flowering of innovation unlike anything seen before."[38] The return on investment in terms of improved health under the Bayh-Dole system has been estimated to be 15 times the annual investment in NIH research.[39] Bayh-Dole has generated continuing streams of income for universities and research institutes, leading to increased funding for scientific research.[40] In the fiscal year of 2002, more than 37 billion dollars in total funding was distributed to over two hundred research institutes in the U.S.[41] In 1999 alone, the licensing and development of these discoveries added $40 billion to the U.S. economy and supported more than a quarter of a million jobs.[42]

The primary social benefit of these two developments was the launch of the biotechnology revolution that has brought so much hope of new cures and therapies for diseases in our lifetime. Most of the commercialization of scientific breakthroughs under Bayh-Dole have taken place in the life-sciences, where products and processes reduce pain and suffering and save lives.[43] It has been estimated that there are thousands of new products on the market due to Bayh-Dole. These include technologies instrumental to the biotechnology industry such as recombinant DNA technology, the process for inserting DNA into cells, new and more effective tests and therapies for cancer and osteoporosis, new vaccines, environmentally sound technologies and even safer guardrails for highways.[44]

Relevance of Bayh-Dole for future ABS Framework

One way to measure the success of the Bayh-Dole Act is the level of private sector investment in the commercialization of biotechnology and the development of the U.S. biotech market relative to the market outside of the United States:

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[36] The Bayh-Dole Act: A Guide to the Law and Implementing Regulation, Council on Government Relations (COGR), 1999 (http://www.ucop.edu/ott/bayh.html). The Economist notes that, "although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return". In *Innovation's golden goose*, The Economist, December 12, 2002.

[37] *Bayh-Dole Act*, Cornell Research Foundation, Inc. (http:://wwww.crf.corell.edu/bayh-dole.html)

[38] Ibid.

[39] *The Benefits of Medical Research and the Role of NIH.* U.S. Congress Joint Economic Committee (JEC). May 2000.

[40] "Running royalties on product sales were $1.005 billion", in FY 2002, according to Patricia Harsche Weeks, 2003 – 2004 President of the Association of University Technology Managers (AUTM), and Vice President, Planning and Business Development, Fox Chase Cancer Center, Philadelphia, PA, A Message from the President, AUTM Licensing Survey, FY 2002.

[41] AUTM Licensing Survey, FY 2002, p.1

[42] Id.

[43] The Bayh-Dole Act: A Guide to the Law and Implementing Regulation, Council on Government Relations (COGR), 1999 [http://www.ucop.edu/ott/bayh.html]

[44] Ibid., Op. Cite.

> [T]he U.S. dominance is clear on virtually any measure. By end-2002 its biotech sector had 10 times the market capitalisation of Europe's.....and the U.S. spent three times more on research and development. This year the gap has widened. In the U.S., biotech has once again found favour with venture capitalists, raising $8.52bn so far, says research group Windhover Information. The rest of the world raised $1.37bn.[45]

The relatively low level of investment in biotechnology outside of the U.S. and Europe may have parallels to the area of natural product development in the developing world. It is not clear, to say the least, how bio-diverse developing countries plan to foster successful indigenous biotechnology industries without doing more to attract foreign direct investment, which is currently being drawn to the U.S. due to the strength of its private rights, including intellectual property rights. The U.S. experience in launching the biotechnology revolution should not be dismissed as irrelevant to the task facing CBD negotiators meeting next year in Bangkok, Thailand. They may want to revisit their current assumptions and positions and move to an "International Bayh-Dole" model as the way to actually advance their development goals and improve economic growth prospects for natural products research and development.

Recent patent data[46] confirms the inadequacy of current incentives for private industry, whether in the U.S., Europe or the developing world, to lower the risk and enable substantial capital investment needed for natural products R&D, including technology transfer and capacity building in CBD developing-country members. The International Bureau of WIPO reports that during the calendar year 2002 alone, it received 114,048 applications filed worldwide, with nearly 45,000 from the U.S. alone.[47] Of these, only a total of 156 patents published over the two-year period between January 2002 and November 2003[48] were for international applications for medicinal substances derived from plants.[49] Despite overall developing country gains in the international use of the Patent Cooperation Treaty (PCT), it should concern bio-diverse countries that WIPO reports very low rates of filing for international patent applications for medicinal substances derived from plants.[50]

Essentially, the bio-diverse developing countries are facing today the same situation that the U.S. faced in the 1970's. They possess a tremendous unexploited potential value in natural products R&D, although without the proper legal framework needed to ensure the commercial development of actual products, their economic development and health objectives will not be realized.

Conclusion: More questions, few answers

This is a story in search of an ending. The next chapter may be written in Bangkok, Thailand, early in 2005, when CBD Members are scheduled to meet for as yet undefined ABS negotiations. At this juncture, all CBD members have a new opportunity, as well as an obligation, to attempt to change the current negotiating dynamic, which has led to the current stalemate over the commercialization of natural products R&D. To the international research-based industry, this means looking beyond patent-based ABS systems for a transparent, predictable and reliable approach (possibly non-statutory) that would provide sustainable, mutual benefits to CBD members, scientists, indigenous peoples and industry.

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[45] Griffith, V. 2003. *Biotech reaches a turning point in its evolution*. Financial Times, December 17, 2003: 16.

[46] Actual patent applications are an independent indicator of commercial R&D.

[47] Yearly Review of the PCT: 2002, WIPO *[www.wipo.int/pct/en]*
In the narrower category of high-technology patent applications, the U.S. Patent and Trademark (PTO) (over 100,000 patent applications) the European Patent Office (EPO) (over 20,000 applications) and the Japan Patent Office (JPO) (85,000 applications) receives the lion's share of total applications for so-called high technology patents for calendar year 2002 (including but not limited to biotechnology patent applications) [http://www.european-patent-office.org/tws/tsr_2002/pdf/high_tech_applic-10.pdf]

[48] Ibid.

[49] International Patent Classification sub-classes A61K 35/78, 35/80, 35/82 and 35/84), cited in WIPO/GRTKF/IC/6/6, November 30, 2003, p. 12. While the number of patents filed in a given year is not directly related to the number of published patent applications during that same time period, this does provide a strong indication of patent trends over time.

[50] International Patent Classification sub-classes A61K 35/78, 35/80, 35/82 and 35/84), cited in WIPO/GRTKF/IC/6/6, November 30, 2003, p. 12.

> It remains to be seen whether the North-South rhetoric of past CBD negotiations, which have not led to any meaningful benefits, will continue to trump the interests of indigenous peoples living in mega-diverse environments, who would gain from greater commercial investment in natural product development. It is hard to over-estimate the importance of this and other related questions for the development of biotechnology hubs in the developing world. As noted above, patent-disclosure approaches adopted to date have failed to bring any benefits to CBD members, and in fact have helped to drive down industry demand for natural products.
>
> Questions that remain include: How will CBD negotiators in the ABS talks view the private sector as an important stake-holder, given the unique role of companies in commercializing science, as demonstrated by the role they played in the U.S. Bayh-Dole biotechnology revolution? Will the ABS talks strengthen accountability and the rule of law systems, like patentability for genetic resources (needed to attract foreign direct investment and encourage technology transfer), or will they lead to a greater understanding of the need for predictability and transparency as a condition for economic growth and stability? The international research-based industry supports a positive approach to ABS that will provide sustainable mutual benefits, through the greater use of contracts that would provide early benefits in the form of technology transfer and capacity building for developing country CBD members. In order to better define operational mechanisms that could bring real benefits, greater dialogue and interchange is needed between all relevant ABS stakeholders.

Before coming to any conclusions or even defining the desired outcomes for the negotiations, it is important that all CBD members be willing to pose the right questions. As Lewis Carroll noted, if you do not know where you are going, any road will get you there.[51] Now more than ever, it is important for the developing country members of the CBD to identify their destination in terms of their strategic commercial interests, and map out a strategy for reaching their goals.

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[51] Lewis Caroll, *Alice in Wonderland*, ("One day Alice came to a fork in the road and saw a Cheshire cat in a tree. Which road do I take? she asked. Where do you want to go? was his response. I don't know, Alice answered. Then, said the cat, it doesn't matter.")

DISCUSSION PAPER
The Smithsonian Institution: The life of natural history museum specimens

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Introduction

The natural history museums of the world are a mixed bag from small, local, organizations dedicated to single taxa to global reference collections. However, the vast majority of them pursue basic science research on taxonomy and systematics: understanding the variety and variability of life. Perhaps no group of organizations or researchers has been more impacted by the access and benefit-sharing discussions (ABS) under the Convention on Biological Diversity (CBD). Movement of specimens across borders is an important aspect of access. It is fundamental in taxonomy (the describing and naming taxa) and systematics (studying the evolutionary relationships between species).

The museums of the world have collaborated for centuries — sharing collections, loaning specimens for research and education, and collaborating in the field and the laboratory. The ABS process has seriously undermined these fundamental and necessary collaborations by making it difficult to impossible to collect or legally move new or existing specimens.

We hope this short paper will explain how basic research collections organizations work, and why ABS regulations should be modified to facilitate taxonomic, systematics and ecological research. Burdensome, regulatory systems impose costs that far exceed the benefits, and even more importantly, transfer those costs to the provider or/and organizations least able to bear them. Systems that do not recognize how basic science works reduces the efficiency of these scientists who the leaders of the world have acknowledged as being too few already.

Demystifying the use of Specimens and Collections

The ABS discussions enable the nations of the world to negotiate rules and processes that protect their rights to fair and equitable sharing of benefits from the utilization of genetic resources. However, a narrow focus on the admittedly important area of disclosure of origin for patent applications and subsequent commercialization of genetic resources has inadvertently created a simplified and simplistic model of specimen use.

> First, this simplistic model regards all collecting as commercially oriented. Second, it assumes a short lag time between collecting, research, extraction, product development, and patenting of that specimen. While this model may fit a small amount of collecting targeted explicitly at bioprospecting, it does not fit basic taxonomic and systematic research, nor most ecological research or monitoring. It also does not reflect much of the plant and animal breeding research, but this topic will not be addressed in this paper.

Natural History Collections – the real world model

Scientists unanimously agree that most of the species of the world are not as yet described and named. Basic discovery, analysis, and naming of the biota is the core work of natural science collections organizations (not all are museums, but we use the generic term museums to cover them all). The first step in this research is to access, e.g. find, discover, or locate unknown biodiversity *in situ*. Historically, collectors gathered and preserved many specimens in the field. Field trip costs (financial, personnel, logistical) were sufficiently high that scientists collected as much as they could, knowing that some specimens would be studied only decades later. Indeed the majority of baseline information on most of the world's biota and ecoregions resulted from subsequent study of these "latent" collections.

Increased ease of international travel and heightened sensitivities to large collecting trips, has made scientists in many specialties calculate carefully just how many specimens are necessary to answer the questions at hand, be it taxonomic, systematic or ecological. Therefore, researchers nowadays seek to limit the numbers of specimens collected. The minimal collection size necessary for taxonomic research varies widely with taxonomic group. For lesser known groups such as invertebrates, relatively more specimens are required to solve taxonomic problems; for well-known groups such as mammals or birds, only one or a few specimens may effectively answer the question posed.

Why are many specimens required? Why is one specimen generally not enough? Just as all humans do not look alike, there is variation among individuals in other species. No matter how similar, two specimens always differ in some characteristics (morphological, physiological or genetic) and those differences do sometimes denote distinct species. The only way to tell if such differences are species or population-level variation is to examine a sufficiently long series of specimens from throughout the species range. For example, ideally, the series should reflect variation in males, females and juveniles. The series enables full description of intraspecific variability and precise differentiation of closely related species. Such work is crucial to prevent misidentifications and to discriminate cryptic, sibling, or semi-species properly.

Such comparisons require loans from other museums. For example, a potentially new butterfly species from Brazil will probably be identifiable to family and genus based on existing literature. Furthermore, the literature may document a very similar butterfly species known only from Peru and Costa Rica and may also indicate which collections may house those specimens. The Brazilian specimen must be directly compared with to the Peruvian and Costa Rican specimens to resolve its status. To obtain them, a scientist must either visit those museums or request a loan. Loans are obviously far more cost effective and efficient than visits and thus the free movement of specimens between taxonomists is crucial to the continued existence of this science. Many of the ABS rules either do not make allowances for such exchanges or impose increased costs and uncertainties on the borrowing or loaning of specimens for study. Each potentially new species encountered during fieldwork requires such comparisons, thus necessitating further loans and borrows. On average, the Smithsonian requests around 327,000 loans from other collections, and sends about 170,000 loans to colleagues in over 100 countries annually. If taxonomy is going to continue within its existing budget and maintain productivity, a mechanism for material exchange that is clear, expeditious, and cheap, is absolutely essential.

Smithsonian loan forms are clear: the loans are only for non-commercial research. As ABS discussions evolve, we continuously examine our procedures to make certain that we conform to the terms and conditions of specimen movement and transfer and we continue to modify forms and procedures as necessary. Transaction costs of specimen movement must however be minimized. Some current proposals would require constant approval from country of origin/source/legal provenance for transactions; such regulations on purely taxonomic transactions are time consuming and costly in terms of paper work and human resources and should be avoided whenever possible. Clearly, heightened scrutiny, mutually agreeable terms from the country of origin/source/legal provenance, and clear mandates are fully appropriate when material is requested for commercially oriented research and/or extraction of new chemicals or metabolites.

A real life example

We will use Dr. Terry Erwin's (1993) research in Ecuador as an example. Dr. Erwin is well known for his systematic and ecological research. His research has multiple goals, but his collecting methodology is designed to answer ecological questions regarding rain forest species diversity. Subsequently the same specimens are used in finer-grained taxonomic and systematic research.

His basic research on beetles has already multiplied by a factor of 20 accepted estimates of global species diversity. By fogging the canopies of many tropical tree species with a biodegradable insecticide mist and analyzing the fallen specimens, he documented a vastly greater number of new species than anyone had ever expected. From the canopy of a single species of tree Erwin found more than 1,100 species of beetles. Given the specificity of beetle species on trees, and the number of tropical tree species, he extrapolated to conclude a global insect species diversity of 30 million.

In 1993, Dr. Erwin conducted 1,800 fogging events in tropical forests in Ecuador, obtaining approximately 9 million specimens. These specimens continue to be used today for ongoing and new taxonomic and biodiversity research. The project trained Ecuadorian students to sort specimens to Class and Order and when possible to family and genus. All specimens were placed in jars containing "restriction" labels that refer to the mutually agreed terms (MAT) between the Smithsonian and Ecuador. These restriction labels accompany every loan of these specimens to scientists all around the world obligating those receiving the material to the conditions of the MAT.

The Smithsonian returns 20 identified species per family to the Ecuadorian Politécnico University Museum in order to build their collection. Although Smithsonian is agreeable to sending more specimens to Ecuador, space and personnel capacities at the University limit the number of specimens that can be stored and maintained there. The remainder stay at the Smithsonian or are transferred to other natural history collections to improve global reference collections. Nevertheless, the original terms and conditions accompany all specimens.

These scientists, usually world authorities on particular families or genera, further sort and identify the collection, often sending subsets of the original collection to even more specialized experts. Specimens are kept by experts for several years and eventually (often many years later), the material is returned to the Smithsonian. In taxonomy, identifications are done free of charge and frequently the only remuneration for the scientist is that they are allowed to keep 2-3 specimens (when possible) for their collections.

Proposed ABS rules would force museums to archive and review correspondence to reconstruct how many scientists in which countries examined the specimens; the costs of such work will far outweigh the benefits. In the case of Dr. Erwin's Ecuadorian collections, specimens went to 20 scientists in 17 organizations/universities/museums in 4 countries over the last 21 years (Ecuador, Mexico, USA and Canada). Many, however, are still being processed as new research projects are started or new experts appear on the scientific scene. Indeed, the loaning and borrowing of these specimens will continue essentially forever as long as museums are willing to keep and provide maintenance to these collections. Archival storage of the material is essential to guarantee the value of these research specimens for future generations.

Finally, it may be decades or centuries before someone collects in that particular locality again, if ever. Given current trends, the habitat may be greatly altered before anyone can return. The original, serendipitous collection then becomes the only available baseline data for that area to understand human-induced and natural changes.

The Importance of Natural History Collections

As discussed above, the natural history museum "collecting model" is nearly the opposite of the bioprospecting model. Basic questions in taxonomy, systematics, and ecology drive the collecting. One of the many ironies of contemporary biodiversity science and politics, is that due to the low funding for basic science around the world, museum scientists sometimes have to look for funding from sources that have other interests such as commercially oriented enterprises. These field trips need heightened scrutiny and the work on the materials that is commercially oriented needs to be done under clearly negotiated terms of benefit-sharing. This has been done successfully, such as in the ICBG work. We know of no researcher who cannot differentiate between the commercially oriented and the basic science applications that the material may be subjected to. If there were increased funding for taxonomy, these scientists would not need to be put into this mixed, and frequently volatile, position. Collections are seen as resources for the future. Museums preserve collections in perpetuity, legally and lovingly, and from past experience we know that they will be used for analyses that we cannot now even envisage. Museum collections are constantly re-examined as new techniques and technologies of analysis develop. Museum collections continue, and will continue, to reveal more and new information about nature and its processes.

Material transfer agreements should therefore recognize that museum collections are multi-purpose. These purposes include documentation of existence, taxonomy, systematics, natural history (life cycle, habits, habitats, specialized structures, evolution, etc), ecology, and, yes, bioprospecting and commercialization. However, the latter two are very minor elements in museum research and can be carefully delimited by rules consistent with CBD principles while still allowing the bulk of museum research and transactions to continue.

The Obligations of Negotiators

It is essential that CBD negotiators understand how taxonomy is done by whom, where, and why and keep this in mind during their discussions. Museums are generally non-profit enterprises; taxonomy *per se* generally generates no revenue. Increased transaction or accounting costs in taxonomic research, whether from demands for non-monetary benefits (training, equipment, et cetera) or from additional paperwork and permits, cannot be passed on to consumers as they can by bioprospecting companies. These costs come out of a relatively small, and if anything, decreasing resource pool. The net effect is that less taxonomic research gets done, the "taxonomic impediment" burgeons, and sub-optimal natural resource management decisions are made, money is wasted due to misidentification, and opportunities are lost. Taxonomy is basic to all research, conservation, and bio-industry; correct taxonomy benefits everyone. All developed countries and their museums have recognized the need for the sharing of non-monetary benefits, and indeed practiced this type of benefit-sharing well before the CBD occurred and increasingly after its ratification. Major world museums are completely committed to training and institution building. To maximize taxonomic and training benefits, we believe transaction costs should be minimized.

The solution is a dual track system: expedited transactions for basic science (regardless of its funding source) and heightened scrutiny and increased obligations for applied and commercially oriented research. A generic material transfer agreement (MTA) that allows for free movement of specimens for basic research is imperative for the survival of museums and non-commercial research.

The Obligations of Museums

Natural history organizations do need to be more proactive in revising their internal regulations and practices to make them clear, transparent, and consistent with CBD principles. The Royal Botanical Gardens at Kew spearheaded such a process for the botanical community, as did others for zoological and microbial communities, but best practices should be summarized and disseminated widely.

Within North America, the Natural Science Collections Alliance has begun the process, and in Europe the Consortium of European Taxonomic Facilities (CETAF) is an appropriate vehicle. These and other appropriate organizations should collaborate and coordinate closely to move forward this program.

The Obligations of National Implementers

The importance of prior informed consent (PIC) or mutually agreed terms (MAT) is not in dispute. However, the implementation of these concepts at the national level has not always been practical, easy or consistent. As an institution that transacts with most countries in the world, the Smithsonian must navigate the rules and regulations of each of these countries. PIC and MAT transverse multiple parts of every government's administration. These concepts minimally include research permits, collecting permits, export, and import permits. In most countries, different offices, even different Ministries, have the responsibilities for some or all of these permissions. Research on lands managed by local and indigenous communities, or based upon their biodiversity knowledge can require additional agreements (not formal permits, *per se*). It is naïve and simplistic to believe that the different concepts and implementation of rules underpinning PIC and MAT can be delegated to a single authority in most countries.

A clear, transparent, low-cost process to obtain appropriate permits and to transact specimens in basic science research is required. Since the vast majority of collecting and specimen shipment is for basic research, most permits, certificates, and/or other documents apply to non-profit uses. Tracking these events falls to government agencies on the one hand, and museums and research centres on the other. Commercial organizations will ever only manage a small fraction of events. The costs of compliance will fall on those least able to afford it — governments of Megadiverse countries and non-profit museums and research organizations.

Closing the Circle

Most new collecting of biological specimens today serves the basic sciences of taxonomy, systematics, natural history and ecology. Paradoxically, most of the discussion in the international community focuses on the small percentage intended or used for commercialization. This fundamental incongruity needs to be addressed as negotiations continue.

Each of the key players has roles and responsibilities to improve transparency and appropriateness in international regime. Understanding biodiversity, developing the fundamental information to support conservation, sustainable use, and equitably shared commercial benefits are all based on the non-sexy, non-profitable, yet fundamentally important basic sciences of taxonomy, systematics, natural history and ecology.

Perhaps we need to develop a principle of Taxonomists Rights, similar to Farmers Rights in the International Treaty on Plant Genetic Resources. Recognizing that taxonomy is based on principles and practice of access and exchange rather than exclusivity, the CBD could go far in addressing the current bottleneck on taxonomic research and begin to free up capacity to overcome the taxonomic impediment, if the COP clearly reiterated its advise to Parties that access for taxonomy, systematics, natural history and ecology is needed for the success of the Convention.

DISCUSSION PAPER
Access and Benefit-sharing: the Role of Scientists

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Scientists in both developed and developing countries need to play a pivotal role in developing an effective international ABS regime. Scientists and their research institutions represent the primary actor by which most benefit-sharing will be achieved and through which much of the current and future access will take place.

Benefit-sharing by scientists occurs through indirect and direct means. Research leading to greater understanding of ecosystems and species or scientific advancement can result in benefits to all of humankind. Direct benefits often consist of the provision of local services (accommodation, transportation, employment) and the transfer of science, know-how or technology to research institutions in source countries. There is a collective interest in ensuring that scientific research and the resulting benefits are not diminished under an international ABS regime. Scientists will also have a significant role in any financial benefit-sharing since the development of commercial applications from genetic resources used for scientific purposes will generally trigger contract provisions to negotiate royalties.

Work by Russell Barsh suggests that national research institutes and universities often provide access to their country's genetic resources. An illustrative example of national research institutes providing access to genetic resources and associated traditional knowledge is the Hoodia plant. The San people have traditionally used the Hoodia plant during hunting forays into the desert. Following the patenting of the active ingredient P57, the Council for Scientific and Industrial Research licensed the patent to the biotechnology company, Phytopharm Plc, which then signed a licensing agreement with Pfizer Inc.

National research institutes and universities are important to the process of the transfer of technology and know-how, so scientific partnerships and networks generally are to be encouraged. The challenge for countries is to create awareness amongst its research institutes and scientists so as to integrate their research activities into the national ABS system.

Some preliminary evidence is that there is little awareness of ABS amongst most Canadian scientists. Research by Canadian academics is underway on a herb (Buckthorn) and a pesticide (pepper corn) that had been accessed in other countries without apparent awareness and compliance with national PIC or MAT procedures. Another issue of concern in Canada is the potential conflicts between the research codes of conduct of government agencies/research institutions/universities and their policies on the institutional ownership of intellectual property rights of their researchers. Accordingly, there is a need to not only raise awareness of potential criminal and civil liability but also to promote best practices through the establishment of codes of conduct for scientists as both "providers" and "users".

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[1] The views expressed are solely those of the author.

In meetings with Canadian provinces and territories, concerns were raised that Canadian graduate students studying in the United States appear to be an important source of exports of Canadian genetic resources. Concerns have been raised that significant samples and information on species are being stored in American universities and that it would be desirable to repatriate some of this knowledge. When creating awareness of ABS amongst scientists it appears that awareness raising efforts should also be extended to graduate students.

Codes of conduct may be developed at the institutional level (e.g. university, botanical garden), the association level (e.g. botanical gardens, ethnobotanists), the community level (e.g. indigenous and local communities), and the national level or international level. In certain countries, national codes of conduct can be especially effective if academics must comply with such codes in order to qualify for funding from national research funding councils.

There may be merits in negotiating an international voluntary ABS code of conduct for scientists under the CBD, as an element of the international regime. Such a code of conduct could raise awareness of ABS amongst international and national scientist associations, as well as improving the level of compliance with national ABS laws. Another desirable aspect of developing a CBD code of conduct for scientists is that the code would be fair and balanced if the key stakeholders —governments, scientists, indigenous and local communities and industry— are all present at the negotiating table.

DISCUSSION PAPER "Genetic Resources" and "Utilization of Genetic Resources": A Legislative View

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In numerous workshops and other meetings with legislative specialists around the world, *The ABS Project*[2] has identified one central important shared obstacle to the adoption of ABS implementing legislation – the need for clarification about the nature of 'genetic resources'. This need is increasingly recognised in discussions about the international regime.

The Objective

To create a functional ABS system, it must be clear what that system covers. Without legislative clarity,[3] a law faces two primary risks:

- the courts, officials, etc. may not be legally able to implement/enforce the law; and/or
- to avoid nullifying a law, courts and agencies may create 'loopholes' (special exceptions and interpretations).

So the first implementation question in law, policy or contract is "What resources and uses are covered by ABS requirements?" This question has not been answered yet. Only a few components of this answer are agreed, specifically:

- There is a difference between 'genetic resources' (GR) and 'biological resources'
- *ABS applies to GR* while the rest of the CBD applies to 'biological resources.'
- There are two operative elements/activities of ABS:
- reasonable[4] 'access' to GR; and
- sharing benefits where there has been 'utilization of GR'.

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[1] This paper presents the views and 'expert input' of the author only. It does not, in any way, represent the views or policy of IUCN, its members, commissions, or secretariat.

[2] "The ABS Project" is a 3-year initiative of IUCN's ELC and funded by the Bundesministerium für wirthschaftliche Zusammenarbeit und Entwicklung (BMZ), undertaking detailed professional research into legal issues and impediments that have slowed and stopped ABS progress. It works with eminent legal experts and partners, including FAO, the Fritjof Nansen Institute, ICIPE. INE, INRENA, IPGRI, IUCN ROSA, SPDA, UNEP, UNDP, UC Davis, and others. The work of the researchers, including the author, do not necessarily represent the opinion or policy of any of these entities.

[3] This paper uses the term 'legal regime' to refer to a system that can be legally enforced and interpreted. If a system merely *allows* ABS compliance as a voluntary or charitable act, these discussions do not apply.

[4] Without using the term 'reasonable,' the CBD imposes reasonability requirements by (i) allowing a Party to limit access to "environmentally sound uses"; and (ii) (classic 'reasonability') forbidding the Parties from imposing restrictions that run counter to the objectives of the CBD.' Art. 15.2.

Clearly, to create an implementable ABS system, one must know if GR are involved, and what constitutes 'utilization of GR.'

The Problem[5]

On the face of it, CBD definitions of *genetic resources* and *biological resources* are functionally identical. A 'genetic resource' ("any material of plant, animal, microbial or other origin containing functional units of heredity [that is] of actual or potential value") essentially means "any living thing". An analyst looking for distinctions may not find any example of a *biological resource* that is not also a *genetic resource*.[6]

Options

The primary triggering actions of ABS are 'access to GR' and 'utilisation of GR'. These are linked concepts – a very broad definition of GR can be clarified and limited by careful delimitation of the actions that constitute 'utilisation of genetic resources.'

This indicative table describes possible relationships between GR and 'utilisation of GR'

'Genetic Resource'	Issues/Comments	Utilization of Genetic Resource[7]
Option 1: GR and 'biological resources' mean the same thing.	(i) Will an 'ABS arrangement' be required for all transactions invol any specimens[8] of any biological resource?	If 'yes', then any utilisation of any living resource is a 'utilization of genetic resources,' including purchase and sale of agricultural produce, domesticated animals, seeds, cuttings, veterinary or research samples, samples taken as evidence of conservation or other criminal or civil violation, etc. By law, this would mean that the benefits of these uses (proceeds of their sale) must be shared under an ABS regime.
		To make this manageable some kind of expedited process would be needed to ensure that conventional transactions (conventional utilization of GR) are not affected.
	(ii) If application of ABS is limited, what standard will be used to decide when an ABS arrangement is required?	'Utilization of genetic resources' could become a new defined term. It could state that only certain uses or types of uses of biological resources are included in ABS. Uses not included (existing conventional contractual and commercial systems) would be addressed under existing legal rules (it might be necessary to define 'conventional contractual and commercial systems', *see* below).

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[5] Recalling that "papers should not be introductory in nature, since participants to the workshop are experts on these issues," this is included because the author was recently called to explain this issue to one she considered an expert.

[6] In theory, an 'ecosystem,' which does not have its own DNA but is included in the definition of 'biological resource' might be one. Legal principle of statutory interpretation provide many bases for concluding that GR is not simply 'biological resources minus ecosystems'. These issues are discussed in a forthcoming legal analysis by The ABS Project.

[7] Arguably, Article 15 was not intended to revise all aspects of commercial transactions in biological materials, including some or all conventional animal and plant breeding. It might be useful to identify the gaps\inequalities Art. 15 addresses.

[8] In the context of ABS, every specimen might be important, since most genetic/biochemical development is based on particular subspecies or varieties, which are sometimes not separately recorded in taxonomic systems.

Option 2: GR refers to genetic material (as a tangible commodity)	Given that physical genetic material (DNA and/or other proteins) are present in all life forms, how are GR transactions distinguished from other trade in biological resources?	*Possibility 1*: ABS compliance only required for movement of prepared samples (for example, specimens in test tubes, or "preserved, dried or embedded museum specimens, and live plant material which carry a label issued or approved by" appropriate government authority[9]). Under this option, most GR would not be ABS. *Possibility 2*: GR includes DNA movement in any form (including whole animals, plants, seeds, etc.). In this case, we again need a definition of 'utilisation of GR' limiting application to particular uses (see Option 3, below).
Option 3: GR refers to 'genetic information' – *i.e.*, characteristics and conditions that can be expressed on paper, as they exist in specimens	Under this definition, even one who did not take any physical material from the source country would still be a user of GR, if he obtained or extracted: - DNA sequences (formulas describing DNA scientifically), or - chemical formulas describing the biochemical properties of the variety/subspecies for purposes of replication. Under this approach, obtaining specimens would also be obtaining 'genetic information,' however, only if one 'utilizes [or intends to utilise] GR' would he need to comply with ABS.	It may be that in this case, no special definition of 'utilization of GR' would be needed. The normal meaning of 'utilization', although very broad, might be sufficient when coupled with a definition of GR derived under Option 3. It could be useful, however, to give some guidance on what kinds of uses are 'conventional uses of biological resources' and therefore not covered by ABS. For example, which of the following are 'uses of genetic resources,' and which are 'uses of biological resources'? BR GR specimen collection c c analysis/ inventory c c removal from country c c transfer to/sharing with others (individuals, entities, agencies, etc.) c c testing/laboratory use (domestic) c c testing/laboratory use (int'l) c c inclusion in public database, taxonomic listing, etc. c c product development (domestic) c c product development (international) c c sale of products using or created with use of GR c c
Option 4: GR refers to 'the right to use genetic information'	Defining GR as a 'right of use' helps clarify Art. 15.1's express restatement of national sovereignty over GR.	If GR is a 'right of use' then the utilization of this right could be inherently clear. Guidance (Option 3) would still be useful. One who needs 'access' to this right must negotiate under ABS law. However, one who intends only to use the resource in a conventional way, covered by other law, will not need to obtain ABS provisions.

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[9] The quoted language is from CITES, Art. VII. 6, under which such samples are excluded from CITES requirements.

Post script: Why address this Issue in the International Regime?

Normally, when legislative draftsmen are called to develop laws that implement policy statements,[10] they find ways of 'translating' the policy language into legislative (operative) language. The policy-makers ask for controls on the use of 'genetic resources' and the legislators determine how that term can be realized in practical principles and regulated.

This process also usually occurs in the implementation of international agreements to which the country has adhered. When this happens, a true 'international regime' develops – that is, by analyzing the various national laws implementing the objective, international tribunals and international law experts can begin to discern common practices and understandings that can be applied across the entire global range of the concept.

Up to now, this process has not happened in the context of ABS, however. Fewer than 10% of CBD parties have adopted functional provisions for ABS, and nearly all have either used the Convention's definition of genetic resources, without explanation, or have modified it to increase its breadth and ambiguity (by extending it to all 'biological resources' for example.)

This difference may arise out of several facts:

- the full meaning and coverage of 'genetic resources' under the CBD is unclear. Parties avoid adopting national definitions, fearing to unintentionally narrow or limit their rights;
- ABS, as an international issue, may be interpreted by courts in other countries, who might misinterpret any unique provisions that are included in ABS law, and
- as an international system, ABS seems to need some trans-border consistency in these basic definitional matters. If one country's ABS system uses one approach to coverage questions, but the system in another country or an area outside of national jurisdiction uses another, it is possible that ABS arrangements will suffer.

Consequently, it would be very useful, for purposes of implementation, if the negotiations provide some guidance in how these issues should applied consistently.

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[10] By nature, all international environmental agreements are policy statements that must be implemented by the adoption of national law.

Section IV. Instruments/Tools/Measures which could assistin Achieving the International Regime including mechanisms for monitoring and/or verification.

A. Certification systems: Product and Process Certification Including Certificate of Legal Provenance/Source/Origin

Elements for the Design of a Certificate of Legal Provenance

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The Convention on Biological Diversity (CBD) recognizes States' sovereign right to their natural resources and their authority to determine access to their genetic resources. As such, access to genetic resources is subject to the legislation of each country. However, the Convention does not consider the provisions needed to address the fact that genetic resources are often used internationally. Likewise it disregards the fact that violations to access conditions would likely take place outside the jurisdiction of the country providing such resources. In order to meet access conditions of source countries, the Convention does not establish obligations for countries with users of genetic resources under their jurisdiction. This omission in the Convention has created an imbalanced system in which the regulatory burden is taken up by source countries as opposed to the countries with users of genetic resources in their jurisdictions.

The problem is not only about who must regulate the country providing the resources or the country with the users, but it is also a matter of how, and what aspects of, the product development chain must be regulated. The fact is that most countries are designing their legislation with provisions made exclusively at the stage of biological material acquisition. This legislation neglects the following issues: control and monitoring issues at more advanced stages of genetic resources' development and innovation; development and trade of their derivatives; and failure to ensure the fulfillment of access conditions when resources are used in other countries. All of these aspects truncates the regulatory chain and reduces the credibility of any threat of legal action against illegal access or misappropriation of genetic resources.

What would happen if countries included measures to support the fulfillment of legislation of those countries that granted access to their genetic resources? In principle, ensuring the fulfillment of foreign legislation may involve high transaction costs. The basic principle underlying the Certificate is to serve as a means to send a legally recognized signal that access has taken place in agreement with legal conditions. In particular, these legal conditions would be those of the source country and access would take place in accordance with international obligations. This certificate would be issued as part of standard procedures for access granting in the source country and would have international validity. It is this feature that allows the certificate to act as a mechanism to convey credible and standardized information through the legal systems, and thereby reduce verification costs. Countries with users within their jurisdiction would take measures to monitor and verify the existence of a Certificate for genetic resources possession. To the extent that these countries enforce these measures a more effective balance of the regulatory cost would take place.

What would be Certified?

There are several concepts that have been proposed, all of which are found in the decision of the CBD to initiate negotiations on the International Regime. These concepts are provenance, origin and source. Origin and source are similar concepts, both referring to the supplier of the material and not necessarily to the process that the material underwent. In CBD jargon, the origin tends to be interpreted as the country that has certain genetic resource in *in situ* conditions; whereas the source only denotes the organization or country that granted access to the material, where this could be an *ex situ* material provider. In the case of *provenance*, this concept tends to be more inclusive. In fact it refers more to the history of custody of the material, described since its first access, including the changes that it has suffered.

Recalling the fact that genetic resources are materially transformed (from biological samples, to chemicals to information), it is important that the certificate be capable of adapting to these characteristics (ie., not only be passed along the various forms of the same genetic resource) and that it should be feasible to reproduce it if more than one product is derived from a single genetic resource. In this sense, it should be more of a tracking mechanism and, as such, it is truly a Certificate of Legal Provenance rather than source or origin? Because these transformations can occur at different instances and places and be done by different agents, the certificate must be internationally recognised - of simple transferability across different users - and use, as much as possible, the existing tracking and monitoring mechanisms to ensure that its administration costs are low.
Conceptually, the Certificate could simply take the form of a number or code that is attached to all documentation involving a particular genetic resource and that can then be checked against a central clearinghouse of certificates, available for verification purposes, and which would contain the specific conditions for accessing the genetic resource.

Reducing the Certificate to a code would greatly reduce administration costs, since it could be added to existing mechanisms used by academia and industry to keep track of their materials, while the Clearinghouse would enable not only providers, but third parties to contribute to monitor the process. There are, however some considerations worth noting at this stage. The fact that someone displays a Certificate or a certification code, does not necessarily mean that the conditions for access have been complied with, but merely that prior informed consent has been obtained and that some form of mutually agreed terms have been reached. Assessing whether the conditions have been satisfied requires further investigation and would require the use of the Clearinghouse to obtain the specific conditions for those materials. The next section discusses the desirability of different modalities of monitoring and verification of compliance.

Check-points for the Certificate: Where and How should the Certificate be Verified?

Two criteria for the identification of Check-points are the transaction costs involved in the monitoring and the enforcement effort and efficacy of the specific checkpoint. In principle, excessive control across a multiplicity of checkpoints can inhibit transactions or even motivate illegal activities. With uncertainty and low success rates being part and parcel of the nature of new product development in biotechnology, the higher the costs of such searches and the more limited they are allowed to be would reduce the possibilities of success and of generating benefits. This could be particularly damaging for non-profit activities. On the other hand, too few check-points would translate into too few or no incentives for compliance. Therefore, the development of a certificate requires careful design to allow for limited but effective checkpoints.

One possible solution is to establish control-free areas where no verification would take place, although the Certificate would still need to be passed along. This area would need to be where transactions are more frequent, but involving the lowest-value genetic resources, i.e. those involving the most basic research up to the identification of potentially valuable derivatives. The creation of these areas of verification exclusion has a two fold rationale: on the one hand they will avoid high verification costs given the multiple transactions, but also, they will avoid verifying at a regulatory point where, given the low value of genetic resources at that stage, users would not face a great penalty and therefore have a lower incentive for compliance. It should be noted here that border controls, in the form of CITES permits, as a means of verification would not be desirable under any circumstance.

The fact that there could be areas of no verification does not mean that no changes in existing practice be needed. In fact, the Certificate or Certificatation code would still need to be passed along. The advantage is that it could be passed along using existing mechanisms that universities and industry use to track their materials, possibly as an annex to material transfer agreements. Likewise, there may be a need for incentives to obtain the required Certificate, particularly directed towards the academic community. For instance, requiring the Certificate when applying for research funding, or when submitting scientific papers for publication, could be considered as incentives for compliance.

Creating "hard" check-points at the end of the product development chain, however, reverses the considerations that limit the use of check-points at early stages of product development. Not only are genetic resources used at later stages of product development far less than those initially bioprospected, but they are also more valuable. This is true in at least two ways: the uncertainty over the value of a genetic resource has been partially resolved and the fact that the commercialization or appropriation is being sought indicates that there is some positive value to the genetic resource; and, in addition, past expenses in reaching to the product represents a sunk cost in the prior bioprospecting effort.

This implies that non- compliance with access and benefit-sharing provisions would have a greater cost for the user, thus creating a greater incentive for them to comply with the legislation of countries providing such resources. Some of these hard check-points could include intellectual property applications and product approval procedures.

There are a number of issues related to the compatibility of requiring the Certificate with existing intellectual property principles that need to be addressed. To the extent that the certificate allows for a clearer description of the invention, the Certificate can be considered as compatible with IP principles and, as such, be part of a formal requirement, which would carry the greatest incentive for compliance. However, if it only becomes an administrative or formal requirement for patentability, the value of the requirement as an incentive depends on the consequences of non-compliance since they need to be sufficiently hard for applicants to face greater costs or, alternatively, lose significant benefits.

A related problem that needs to be solved for the requirement to become a credible incentive is the identification of the trigger points of the requirement itself, i.e. which inventions are sufficiently related to the genetic resource that the disclosure of the Certificate is triggered.

Elements to Consider in the Design of the Certificates

As a result of the above considerations, there are several components that need to be defined for the clear an effective operation of the Certificate of legal provenance:

- designation of national authorities to issue the Certificate and that are mutually recognized;
- identification of conditions for verification and enforcement of the Certificate, that is, which materials, for which purposes, in which moment or at which stage will they be checked, including the limits to derivatives related the genetic resource;
- exclusions;
- provisions for cases where it is not possible to identify the origin of the genetic materials, including on benefit sharing;
- differential treatment for specific sectors;
- mechanisms to solve controversies;
- creation of an international registry for the Certificates;
- treatment of non parties, and

- provisions to deal with *ex situ* pre-convention materials to prevent them from becoming a loophole for the Certificate system.

Advantages and Limitations of the Certificates of Legal Provenance

The Certificate of legal provenance has various advantages that can positively contribute to solving some of the implementation problems of access and benefit-sharing provisions, internationally. For instance:

- It serves as evidence that genetic resources have been obtained in accordance with the access provisions of the providing country;
- It enables the effective application of user measures by reducing their cost of implementation;
- It discourages misappropriation of genetic resources to the extent that they are verified at key check-points;
- Facilitates monitoring by providers and interested third parties, through the use of the Clearinghouse mechanism, and
- Generates greater transparency and confidence for parties in transactions.

Despite this, there are also limitations of the Certificate, i.e. issues that cannot be resolved by the Certificate but which are key problems for the effective regime created around access to genetic resources. For example, the Certificate:

- does not ensure that mutually agreed terms have been complied with;
- does not create an equitable platform for the negotiation between the actors involved (asymmetries in capacity and information are not resolved);
- does not ensure, *per se*, a fair and equitable distribution of benefits, but represents a signal that mutually agreed terms have been reached;
- does not substitute the need to develop national access legislation, since they can only be issued by countries with national procedures for doing so;
- depends on solving the management of *ex situ* pre-convention materials in order for it to be effective;
- it provides a solution only for those who can negotiate i.e it excludes the large number of communities unable to enter into contracts, and
- it does not adapt equally well to all sectors

As a result, the Certificate represents an element of the RI that would still require additional measures to address the limits of the Certificate.

Final Remarks

Certificates are undoubtedly an appealing instrument as an enabler of significant user measures and relevant check-points that will reduce uncertainties and increase transparency and confidence of providers. At the same time, it will provide greater certainty to the users of genetic resources, by giving them a means to proof that they are behaving according to the CBD and the legislation of the provider country.

However, a word of caution is in order, since not any design of the Certificate will be administratively and economically feasible. It should also be clear that the Certificate can only solve part of the problems surrounding ABS. There is no "silver bullet".

Certificates of Origin, Legal Provenance and Source: Mutually Exclusive or Complementary Elements of a Comprehensive Certification Scheme

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David Cunningham and Kazuo Watanabe.

The secretariat to the CBD was tasked by COP-6 to undertake further information gathering and analysis of the feasibility of an international certificate of origin system, as evidence of MAT and PIC for the use of genetic resources. As discussion of the proposal has advanced, so too has debate about what should be certified and proposals have emerged for certificates of source and legal provenance as well. This led COP-7 in 2004 to decide to undertake further examination of an internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge as part of the negotiation of an international regime on ABS.

Once again the feasibility, practicality, operational functionality and costs of any international certificate system were identified as the key issues to be investigated. Investigation will also focus on the potential role certificates might play in a system regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

Despite several preliminary investigations and many informal discussions at international meetings, however, there is still no clear understanding of how a certificate of origin system could operate in practice, or what should be the scope or nature of any such system.

The term "certificate of origin" was originally coined in 1994 to describe a proposal for the use of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources. The original concept proposed the adoption of requirements for disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receipt and processing of patent applications.

It was suggested that the establishment of a standardized certificate of origin, which would act as evidence of prior informed consent, would exempt patent officers from the need to examine all of the documentation related to an ABS agreement to verify compliance with the CBD (Tobin 1994). The idea was quickly taken up by indigenous people across Latin America and the Declaration of Santa Cruz (1994) calls for further investigation of the potential of system of certification of origin to protect rights over traditional knowledge (TK).

It was also included in proposed Draft Elements for a Regional Regime on ABS for the Andean Pact, prepared by IUCN/ELC and The Peruvian Environmental Law Society (SPDA) between 1994 and 1995 (Tobin 1997).

The term has since taken on a wider meaning which broadly encompasses the tracking flows of genetic resources and documenting evidence for the right to use genetic resources. It has also been proposed that such a system could be expanded to apply to product approval processes, scientific publications and other regulatory approval procedures.

Framework for a System of Certificates of Origin

In determining the potential framework of a certificate of origin system, a number of key issues need to be addressed, including:

- The purpose of certification;
- Nature of a certificate, ie. would it be mandatory or voluntary;
- Subject matter covered by the certificate;
- What it is certifying origin, source, or legal provenance;
- When would it be required?;
- What format would a certificate take: physical hard copy, barcode or virtual online certificate?;
- Verification procedure;
- What terms and conditions would apply to material provided under a certificate?, and
- What verification and compliance mechanisms would be needed to support such a system?

These matters can be addressed only briefly here, and focus will primarily be given to addressing the issues of the subject matter to be certified and what is being certified. A proposal is also made for utilizing certificates as a tool for promoting a more flexible access and benefit-sharing procedure that incorporates elements of both liability and property regimes, as discussed by Ruth Okediji in her paper for this workshop.

Subject Matter of a Certificate

A preliminary list of the information that may perhaps be included in a certificate of origin, has been proposed by Barber *et al*. (2003), these include:

- Particulars of the provider and user;
- Particulars of the indigenous or local communities parties to the agreement;
- Details of genetic resources or traditional knowledge;
- Details of the approved use which may be made of the resources;
- Details of any restrictions on use;
- Period of the agreement;
- Conditions relating to transfer of rights to third parties, and
- Details of the issuing authority.

With regard to the provision of details of genetic resources or traditional knowledge the latter is less problematic as particular elements of TK could be clearly identified, while detailing genetic resources may prove more problematic, in particular where the material involved includes unidentified samples made in random bioprospecting collections.

As the focus of the system will be to trace the flow of genetic resources it would seem at first glance that genetic resources themselves should be certified. This, however, is not only impractical it will be impossible in a vast majority of cases where the material collected still remains to be classified. Once again, the issue of the definition of "genetic resources" also comes into play, because there are a multiplicity of possible collections which would fit the CBD definition, including isolated compounds, soil samples, insect collections and animal and plant specimens. Certificates could be granted for the access contract itself and all material collected under it, for a specific collection activity in a defined area for a defined period, for all samples of a specific species or genus, or for an individual collection or sample. At a different level, a certificate might be linked to a particular isolated compound, perhaps be given an individual barcode, as is the case with samples provided by INBio. What will be necessary is to identify the most practical level for the granting of a certificate and develop a system which enables collectors and or users to code the products of research and development in an identifiable manner which links back to the original certificate.

What is being Certified?

The term certificate of origin implies a certificate which identifies that a genetic resource that has been obtained from a country of origin, as that term is defined in the CBD. This has proved problematic for some as identifying the origin of resources may be impossible in many cases, thereby creating a legal limbo for resources whose origin cannot be identified. Proposals have now been made for alternatives such as a "certificate of source" or a "certificate of legal provenance". These proposals are, however, also problematic and have not found acceptance with those who fear the potential implications for collections of genetic resources collected prior to the entry into force of the CBD, or subsequently without any PIC or MAT.

A certificate of source would track the genetic resource only as far as the place where the user obtained it, which may be a collection or depository and not necessarily the country of origin. A certificate of legal provenance would document evidence that the resources had been obtained from a legally entitled provider. In the face of continuing uncertainties regarding legal rights over resources and in the absence of a binding international regime on ABS (which clarifies the legal status of all pre-CBD collections and of those collected post-CBD but without PIC), legal provenance would fail to be decided by the laws of the country where the resources were sourced. This situation could potentially provide an opportunity for circumvention of the rights of countries of origin. A certificate of origin would be granted by a country of origin.

Attempting to secure international agreement on whether a certificate of source, legal provenance or origin is to be the preferred option is a difficult challenge and is, not necessarily, the best avenue to pursue. In fact, a system which employs a variety of certificates including both certificates of origin and legal provenance, as well as, potentially, certificates of source, may be the most effective way to expedite the establishment of a functional international system.

A certificate of origin would most likely be granted by a national competent authority while a certificate of legal provenance would more likely emanate from the provider of the relevant genetic resources such as a genebank, herbaria, etc. Their right to grant such a certificate could be established by a national approvals procedure under which they are listed in a Register of those organizations entitled to grant certificates of legal provenance, for resources within their collection that meet determined criteria. This could include material collected prior to entry into force of the CBD, material collected in accordance with international agreements, or material obtained in accordance with national law in countries not requiring PIC and MAT for access, and for which it can be shown that resources were obtained in full compliance with the national laws and policies of the provider country. Certificates of legal provenance might also be granted by a national authority for resources held by individuals or companies which are not registered, and subject to provision of evidence of their legal acquisition of the relevant genetic resources.

The value of having a separate defined certificate of origin would be to clearly establish a fresh chain of custody for genetic resources obtained in accordance with the CBD's provisions on ABS; add value to resources by ensuring legal certainty for users; and to distinguish material for tracking and for marketing purposes. It is conceivable that resources which are covered by a certificate of origin may in time become more valuable as users seek to ensure the legitimacy of the source and to avoid any potential claims of biopiracy.

Certificates of source would be issued by providers who are not registered for the purpose of issuing certificates of legal provenance. In such a case, the certificate of source would indicate where the provider had obtained the resources and would serve to provide a paper trail of resource transactions, which could be traced for the purposes of identifying whether the resources were legally held or not. This might for instance be utilized for exchanges between scientists for pure research. Certificates of source would therefore be required for all exchanges of genetic resources for scientific research purposes not covered by certificates of origin or legal provenance, and would help to develop a more responsible management of resource flows amongst scientists. Such certificates could not be used as the basis for commercial use of resources, and in the event of serendipitous innovation, it would be necessary to seek a valid certificate of legal provenance or origin prior to seeking a patent or product approval et cetera.

Establishing a system of certification which provides for certification of source, legal provenance or origin from a predetermined date may prove more feasible as a means for launching a comprehensive system for tracking resource flows than trying to establish a single form of certification to fit all situations.

How would a Certification System Operate?

One potential mechanism would be to grant a certificate for all samples collected under a particular contract. The contract would be registered with the competent national authority and would be accessible for consultation with regard the terms and conditions applying to samples covered by the particular certificate.

In such a case the original certificate would specify a contract number which would accompany all subsequent transfers of relevant genetic resources. Transfers would be conditional upon a commitment to notify the competent national authority in the providing country. Under such a system an obligation could be established so that all collections made under the relevant agreement would be coded with the certification number applying to the original contract, to which would be added a number to identify specific collections, samples etc. At subsequent stages in research and development additional codification would be added to identify specimens, isolated compounds, et cétera.

Under such a system, the transfer of resources to third parties, where allowed under the original agreement, would be made subject to the terms and conditions of the original agreement or a set of standard terms and conditions established by the providing country's competent national authority. In this case, a certificate of origin might be likened to a MTA and the certificate of origin would serve to put the recipient on notice that use of the relevant resources is governed by these terms and conditions. In this sense the certificate of origin would serve as a form of shrink wrap licensing regime. The result could be to significantly free up the flow of genetic resources, while ensuring legal certainty for users as to their rights to us resources and security for providers that their resources were covered legal obligations.

It would of course be essential that "user measures" are in place to ensure compliance with licensing conditions. Failure to comply with the terms and conditions of the licences associated with relevant genetic resources would amount to a clear case of biopiracy.

One potential embodiment of a certificate of origin may be likened to a passport that accompanies genetic resources, either through their entire history from collection to use ("cradle to grave") or for certain transactions such as patent applications or product approval procedures. Possible checkpoints for a certificate could be at borders (Figure 1), patent offices or the registration points for other commercial applications not covered by intellectual property rights.

The actual format of a certificate could either be paper, barcoded or perhaps, for organizations carrying out high levels of transactions, by way of virtual online certificates. Notification of transactions and transfers to the providing country by way of an online register of resources would potentially reduce the administrative burden of such a system while ensuring the maintenance of a clear trail of resource disbursements. It may be necessary to develop a system by which resources may be retired and reporting obligations terminated with regard to certain resources, when they are no longer in use.

Disclosure of Origin

Proposals for the establishment of disclosure of origin and traditional knowledge have become part of the mainstream debate on implementation of ABS and TK regimes, across many important forums including CBD, WIPO and the WTO. Mechanisms have been adopted requiring disclosure in numerous countries of the developing world including the Andean community, India, and Costa Rica, as well as in a growing number of developed countries, most notably Denmark and Norway, the latter requiring disclosure of both origin and of evidence of PIC. Proposals have been made by India and Brazil and a host of developing countries at WTO, for amendment of TRIPS to include a mandatory requirement on disclosure of origin. Meanwhile, Switzerland has proposed an amendment to the Patent Cooperation Treaty for a voluntary regime.

The functioning of any disclosure regime will require patent officials to determine whether the origin of resources has been adequately disclosed, and, where appropriate, whether PIC for use of resources existed. It is not hard to see that patent officers will be uncomfortable about assuming responsibilities that may lead to the burdensome and time-consuming evaluation of issues beyond their area of capacity.

A standardized international system of documentation to record the origin of resources and, where appropriate, PIC for their use, would make their task much easier as the document would serve as evidence of both origin and PIC. This does not mean that providers of resources are bound to provide certificates of origin as a condition for granting access to resources, nor that applicants for patents are bound to provide them as evidence of origin or PIC, which could be evidenced by other forms of documentation. However, a streamlined process involving standard documentation is likely to be welcomed by patent officials.

Many products are not covered by patents, however, and other regulatory processes such as drug, seed and other product approval systems, also lend themselves to controlling the use of resources and may help promote compliance with ABS laws. Similarly, if scientific journals were to require evidence of rights to work on relevant genetic resources or traditional knowledge, as a condition for acceptance of articles, this would prove an important inducement for scientists to ensure they have obtained rights to use relevant resources. In all such cases, a certificate of origin could serve to demonstrate the right to use resources.

The benefit of certificates for the private sector would most clearly be to provide legal certainty regarding the right to use resources. Such a system could also help provide greater security for providers when linked to a licensing regime such as has been described above. The development of any certificate system should be carried out with an eye towards promoting greater transparency, flexibility and mobility in the international flow of genetic resources.

Feasibility, Practicality and Cost

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore, any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits. There is already evidence that pharmaceutical companies are withdrawing from natural products research because of uncertainty over access (Dalton, 2004). The number of new accessions to international agricultural genebanks has declined sharply since the CBD was ratified (Falcon and Fowler, 2002), raising concerns for food security. A key question to be addressed, therefore, is whether a certificate of origin scheme would serve to facilitate or further impede access and benefit-sharing.

For both conservation and commercial use, the benefits of any certificate of origin system would have to outweigh the costs. The main benefit for commercial users would be certainty of title to a genetic resource. This is critical to ensure that large R&D investments can be recouped. For non-commercial conservation uses, such as basic biodiversity research, there are many more international transfers of specimens compared to commercial users because no single country has the taxonomic expertise to identify the majority of organisms. In this sector, there are no monetary benefits to support an expensive tracking system and one option that has been proposed is to exempt these uses by creating a special category. Care would need to be taken with this approach to ensure that any exemptions did not create a loophole in the legal system that allowed genetic resources to flow to commercial uses via the exempt sector without renegotiation of an ABS agreement.

To some extent, technologies developed in other industry sectors may be applicable for achieving traceability of genetic resources. For example, systems for monitoring IPRs over electronics, computer software and even music are well developed although instances of illegal use still occur. For some biological products, like agricultural commodities, there are quality assurance systems capable of tracking food from the farm to the supermarket. There already exist a range of international standards for biological products such as sanitary and phytosanitary (SPS) standards, food safety and labelling laws. For some other biological resources that are or have been traded, there is a certification system the Convention on International Trade in Endangered Species (CITES). This is limited to border crossings of a selected number of species when transferred among the 164 countries which are members of CITES, while cases of illegal trade outside the system continue.

For most bioproducts, however, the supply chain arrangements are different to these sectors, the value of most genetic resources is poorly defined hence it can be difficult to demonstrate the benefit of an expensive tracking system, the timeframe from acquiring a resource to deriving any benefits may extend for decades or longer, and, in many cases, it is more difficult to detect unauthorized uses of a genetic resource.

Future Directions for Certificates of Origin

Key questions about certificates of origin include what event would trigger the issuing of a certificate, who could issue it, what happens when a resource may be obtained from a range of countries and knowledge from a range of local communities in one or more countries, would it apply to individual samples or all samples covered by a particular contract or even individual genes, how could the information be stored and accessed, how far could a resource be traced in practice and what measures could be put in place for penalties, liability and redress. A fundamental question is what a certificate system is for, would it help users and regulators to facilitate the continuous flow of genetic resources while at the same time respond to demands for rights to resources and associated traditional knowledge under the CBD? If not, are there alternatives to achieve these outcomes?

UNU-IAS has initiated a comprehensive research program on certificates of origin, which involves collaboration with major collections of biological resources around the world including the Smithsonian Institution (USA), the Royal Botanic Gardens, Kew (UK), INBio (Costa Rica), commercial users of genetic resources in Japan and selected microorganism collections. Case studies of a range of plant, animal and microbial genetic resources are being used as the basis for a comparative analysis of how different institutions are tracking the receipt, storage and dispersal of various kinds of genetic resources. Preliminary results have shown a range of technological and legal approaches to tracking genetic resources. This investigation intends to shed light on the feasibility, practicality and cost of a variety of potential systems for tracking genetic resources, with a view to determining the viability of wider application of these measures to achieve the objectives of both facilitated access and equitable benefit sharing.

The results of UNU-IAS research on certificates of origin will be presented at the Working Group on ABS under the CBD, in Thailand, February 2005. Further information on UNU-IAS work on certificates of origin is available at www.ias.unnu.edu

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DISCUSSION PAPER
Certificate of Origin / Source / Provenance

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A certificate of origin/source/provenance will most certainly play a key role in the development of the International Regime on Access to Genetic Resources and Benefit-sharing, to be negotiated within the framework of the Convention of Biological Diversity (CDB). The idea of having a certification system for genetic resources under the framework of the International Regime seems like a way forward in giving more transparency in access and benefit-sharing arrangements nationally and internationally. This certificate would facilitate verification of compliance with ABS measures as well as support monitoring of the use of genetic resources and in various checkpoints, such as borders and patent applications in both user and provider countries.

However, it has not yet been discussed within the framework of the CBD whether this certificate should be one of origin, source or provenance. I would like to highlight the main differences in my view between these three, particularly between the certificate of origin and the certificate of legal provenance.

The *certificate of origin* would disclose information regarding the country of origin of genetic resources. I would like to highlight that certain countries like Norway have already included disclosure of origin in its intellectual property measures. On the other hand, the *certificate of source* would provide information regarding the place where the genetic material was taken from, regardless of whether this was the country of origin or not, i.e. it could prove it was taken from an *ex situ* collection, without disclosing the country of origin from where it was originally collected form.

Meanwhile, the *certificate of legal provenance* would not only disclose the country of origin of genetic resources, but would also prove that genetic resources and traditional knowledge, where appropriate, where accessed under ABS provisions such as prior informed consent (PIC), mutually agreed terms and benefit-sharing arrangements. This certificate could be issued and controlled by the environmental national competent authority of provider countries.

If the purpose of the certificate is to support CBD's provision in regards to access and benefit sharing, it seems that a certificate of legal provenance would best serve the purpose of tracking compliance with ABS provisions, particularly PIC. Furthermore, this certificate could play a mayor role in the field of intellectual property, whether considered an administrative requisite for patent applications or a requisite for patentability.

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[1] The views expressed are solely those of the author.

ABS Certificate System

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In ABS discussions under the CBD, the concept of certificates of legal provenance/source/origin have been proposed by some as an important element of ABS monitoring and enforcement for genetic resources transported across national borders.

It seems evident that such a system of certificates may include some aspects of various certificate/labeling systems related to international trade, property rights and environmental regulation. There are likely elements of certificate systems governing international trade in products and services (e.g. phytosanitary rules) that may be adaptable to an ABS certificate system. Perhaps, the design and enforcement of certificate systems governing international trade in cultural heritage may provide some insights into how best to design an ABS certificate system. This paper will focus on aspects of certificates that may be modeled on intellectual property rights or the regulation of trade for environmental purposes.

An analysis of the elements of various IP systems may provide some useful concepts for the ABS discussion on certificates. For the most part, enforcement under the intellectual property system is by the IP owner through civil court proceedings. A recent trend in some countries (e.g. United States) has been to increase government involvement in the enforcement of IPRs (e.g. border enforcement, drug approval processes).

The patent system may provide some insights into elements for an ABS certificate system. Patents are granted for inventions at the national level. There is no international patent right nor fully harmonized patent standard between national jurisdictions. The WIPO Patent Cooperation Treaty (PCT) may provide some lessons for international co-operation in making an international ABS certificate system operational, as well as, minimizing regulatory costs. Adapting the PCT model, standard classification systems (taxonomy/genomics), cooperatively developed rules and procedures and electronically searchable databases (e.g. genetic resources, PIC numbers) may be potentially desirable aspects of an ABS certificate system.

Under many national patent systems, patentees of biotechnology inventions are allowed to include the accession number of deposits of biological material to support the public disclosure of the invention. The rationale for allowing deposits of biological material is that access to this material is necessary for generic manufacturers to reduce the invention to practice upon the expiration of the patent. The deposit system under the patent system is of interest for two reasons. Firstly, there may be aspects of design and administration of the patent deposits of biological material that may be applicable to an ABS certification; for example, certain restrictions on access to and use of deposits by experts only. Secondly, it may be appropriate to link such an ABS certificate system to the patent disclosure procedures and associated deposits of biological materials.

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[1] The views expressed are solely those of the author.

An effectively designed ABS certificate system could assist in monitoring and regulating trade in biological resources. It would seem that a goal of such a certificate system would be to achieve administrative and enforcement efficiencies with other environmental regulation. Thus, the certificate system should be forward looking in attempting to integrate trade in ABS-related material with the regulation of international trade in endangered species (CITES), regulation of trade in genetically modified organisms (Biosafety Protocol), phytosanitary regulation of trade in biological material and international efforts related to invasive species. On a practical level, the same border officials are likely to be responsible for overseeing trade in all these types of biological materials. Simplifying any import/export certificate procedures, and facilitating the use of searchable electronic taxonomic databases covering the gamut of regulatory regimes governing trade in biological resources, would seem to be a desirable objective.

With respect to adapting aspects of certificate systems used for environmental regulation purposes, the Convention on International Trade in Endangered Species (CITES) would seem to be the most applicable model. Some preliminary thoughts on CITES/ABS follow.

It is interesting to note that CITES includes monitoring and enforcement at several points in the trade pathway - the source country, borders and the marketplace (e.g. natural products stores). A key element is the use of export and import permits. The CITES model of monitoring and enforcement throughout the market chain would seem to support calls for ABS enforcement measures not only in "provider" countries but also in "user" countries. All countries are both providers and users of genetic resources so all countries will need to take measures to monitor and enforce access to biodiversity, to enforce at borders and to enforce in the marketplace. Therefore, it is in the interests of all countries that the monitoring and enforcement system using certificates needs to be designed in order to achieve system-wide efficiencies.

For several reasons, the monitoring and enforcement of trade in ABS-related biological resources is likely to more challenging than under CITES.

There are approximately 250,000 species currently on the CITES lists. In comparison, estimates suggest that there are more than 14 million species world-wide and only approximately 10 percent of these species are known. ABS-related trade will involve many more millions of biological materials to regulate than under CITES.

Enforcement of unauthorized exporting of small soil samples containing microorganisms is much more difficult to monitor and enforce against than the smuggling of elephant tusks and ivory carvings. The mailing of seeds in a letter and the e-mailing of taxonomic/genomic/proteomic information are additional enforcement challenges beyond those encountered under CITES.

There are also some lessons from CITES that may be useful in designing and administering an ABS certificate system. First, the use of different lists of endangered species with different permit requirements may be usefully applied to deal with scientific/commercial uses, different sectors, endemic versus species that range across borders, etc. Experiences by CITES with the use of taxonomic descriptions and searchable electronic databases should be analyzed for applicable uses under an ABS system. CITES monitoring and enforcement strategies targeting different marketplace actors (e.g. organized smugglers, collectors of exotic species, tourists, etc.), as well as, certain problematic areas (e.g. ivory, bushmeat, shark/bear parts) may have some relevance for the design and administration of an ABS certificate system.

DISCUSSION PAPER
Uses, Benefits, Tracking and Trade-offs — A Botanical Collections Perspective

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Fair and equitable benefit-sharing is a central objective of the CBD and of the International Regime. But with so many sectors seeking access to genetic resources for such a wide variety of potential uses, which in turn may generate many different kinds of benefit, the terms 'benefit sharing' and 'benefits' end up being used in policy discussions as abstract notions. To some these terms represent the whole range of potential monetary and non-monetary returns, while to others they may signify commercially-oriented IPRs, milestone payments and royalties.

Another term that needs closer examination is 'tracking' in relation to genetic resources, especially when considering the practicality and feasibility of certificates of origin/source/legal provenance. As well as considering the type of material to be tracked (e.g. individual specimens, batches, genes, MTAs or other entities), it is very important to be clear about what processes people are proposing to track: transfer? use? benefits? It would be extremely premature to consider tracking individual specimen uses or benefits in the future, and the perceived advantages of doing so rely on an underlying assumption that particular benefits arise directly from the use of particular specimens. It is crucial that we consider possible impacts on conservation and basic research of additional detailed tracking which diverts resources from collaborative work and the delivery of benefits.

To ensure that benefits continue to be created in the first place, and to maximize their utility for conservation and sustainable use, we need to think very practically about how collections work with genetic resources, and what results they produce.

On this note, I wish to provide some examples of benefits that are actually generated by basic research on non-profit botanical collections such as herbaria, DNA banks and living collections, and to explain how they may be shared. I also wish to dispel any idea that individual specimen use and benefit-sharing are frequently coupled. Further, I wish to argue that detailed tracking of specimen use and benefits is extremely resource-intensive, with insufficient benefits to outweigh transaction costs. For non-commercial research, for which the vast majority of specimens are collected, such tracking would be counter-productive to the CBD's objectives, as it would necessitate the reallocation of resources needed for use and consequent benefit-sharing.

The CBD refers to the sharing of benefits arising out of the utilization of genetic resources. In some cases, it is clear that certain uses of particular specimens may generate benefits – interesting compounds or structures may be elucidated, or an attractive plant may be selected for horticultural development. However, I would argue that for most non-profit scientific collections, significant benefits are usually produced in more diffuse ways.

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[2] The views expressed in this paper are those of the author and do not necessarily represent those of the Royal Botanic Gardens, Kew.

Many important benefits (including some set out as examples in the Bonn Guidelines) arise at the **access** stage, rather than through the actual use of particular genetic resources. Capacity-building benefits generally do not come about directly from use, but instead from **institutional services** such as provision of higher education or training programmes which are based on a broad range of collections. Perhaps the most significant benefits for conservation arise out of the **broad and comparative use** of global and regional collections.

Examples of benefits linked with access include monetary ones such as permit fees, but also a whole range of more non-monetary benefits arising from partnership activities. The process of negotiating mutually agreed terms for access and use can provide a chance for partners to identify national and institutional needs and priorities. Finding funding for fieldwork is often a problem for host country institutions, and joint field trips are valuable opportunities not just for enriching in-country collections (it is standard practice for the top set of herbarium specimens to remain in a host country collection, unless otherwise agreed), but for exchanging skills and expertise and for professional networking. There may also be training courses, workshops or other knowledge-sharing opportunities offered in association with joint fieldwork.

The biological collections sector can often provide a wide range of other capacity-building activities, few of which arise from the direct use of particular genetic resources. Staff exchange programmes provide simple but effective opportunities for transfer of skills and know-how. Some institutions have strong educational programmes, and may be able to offer places on in-house courses, or degree supervision. Many of these activities help overcome acknowledged barriers to the implementation of the Convention.

The extent to which these types of access- and education-related 'benefits' can be offered depends on the capacities (expertise, facilities, funding) of the collaborating partners – providers and initial users. We should not expect further users of genetic resources down the chain to share the same benefits with providers, if any scheme to track MTA terms is developed.

But how are specimens themselves actually used back at a museum or herbarium? They are made available to, and examined by, a range of resident and visiting experts, who assign taxonomic names, and these names are sent back to partners in the country of origin to be affixed to the top set(s) (it is vital that collections are well-named, or they have no use). Specimens are filed first by taxonomic affinity (not by country of origin or MTA), and are consulted (i.e. looked at, measured, compared) and in some cases sampled (for characteristic pollen, structures, DNA or other compounds). It should be noted though that many years, even decades, may pass before any single specimen is examined again after its initial collection and identification – this depends on the research interests of present and future staff, visitors, and scientists from elsewhere who request loans or samples of material. Increasingly, but depending entirely on available staff resources and funding, herbarium specimens may be scanned or photographed, and images may be made available in the form of a 'virtual herbarium', and label information may be databased (bearing in mind that some label data may be more sensitive and not suitable for wider dissemination).

Typical research outputs arising from these collections include floras (which pull together and describe all plant species in a given region) and systematic revisions (which explore evolutionary and taxonomic relationships within and between groups). These are important information sources that in turn are used to create useful secondary products such as interactive identification keys, field guides and Red Data Lists.[3] There is a growing range of conservation-focused uses for global and regional collection data. Using GIS technology, location and phenological (time of fruiting/flowering etc.)

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[3] Golding, J.S. (ed.), 2002. *Southern African Plant Red Data List*. Southern African Botanical Diversity Network Report Series, No. 14. pp. 135-156. National Botanical Institute, Pretoria, South Africa.

data gathered from labels can be used to create distribution maps for conservation assessments,[4] vegetation maps for land management,[5] guides to enable efficient location of target species for conservation, and analyses of ecological change over time.[6] Phylogenetic studies can guide efforts to conserve areas with high genetic diversity. Virtual herbaria can be linked to initiatives such as the Global Biodiversity Information Facility, enabling further study by conservation practitioners worldwide.

Projects such as these involve data collection from hundreds or thousands of specimens, which may make some potential scientific benefits, such as co-authorship, impractical below a certain level of basic collaboration and acquaintance. They involve limited use of 'genetic' characteristics —DNA sequences are used to uncover relationships but cannot create new organisms or products. Digitized information (images and data) and conservation tools can be shared with institutions in countries of origin, and all of this research is increasingly initiated and carried out in close collaboration between provider and user country institutions.

Institutions vary in the extent to which they are currently able to track the transfer and use of individual specimens. All institutions can determine where most of their specimens were acquired (though historic specimens may pose problems), and the majority have systems to record where they have sent material (though not necessarily at the level of individual specimens). Some may be in a position to record certain uses (such as sampling of living or preserved specimens), while other uses, such as simple consultation, are currently unlikely to be tracked by any institution. There is increasing use of Material Transfer Agreements as awareness of the CBD has risen, and institutions using MTAs can store these, refer to them, and link their terms to specimens using available systems. However, detailed tracking at the level of individual specimens involves far greater curatorial, administrative and IT investment, and funds for such system change are difficult to find. Though it is important to continue to improve record-keeping, a high priority should be given to continue efforts to raise institutional awareness worldwide and to the development of standard implementation tools such as clear policies, MTAs, and staff training and guidance.

I hope it is clear that there is rarely any point in expecting major economic returns from any one specimen in such a collection. Instead, most benefits arise from long-term partnerships, improved networks and communication, generation and dissemination of conservation tools, and raised awareness of all the responsibilities that come with working on global biological material. When resources are limited it is better to create a strong collaborative framework for research and capacity-building, within which providers are kept involved and informed, rather than construct a resource-intensive administrative system unlikely to provide real benefits, commercial or otherwise.

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[4] Willis, F., Moat, J., and Paton, A., 2003. *Defining a role for herbarium data in Red List assessments: a case study of Plectranthus from eastern and southern Africa*. Biodiversity and Conservation. 12:1537-1552

[5] Du Puy, D., and Moat, J., 1998. *Vegetation mapping and classification in Madagascar (using GIS): implications and recommendations for the conservation of biodiversity*. Pp 97-117 in: C. R. Huxley, J. M. Lock, and D. F. Cutler (Eds). Chorology, Taxonomy and Ecology of the Floras of Africa and Madagascar. Royal Botanic Gardens, Kew.

[6] www.kew.org/gis/projects/mad_veg/index.html

DISCUSSION PAPER

A Simple Solution Using Certificates of Legal Provenance as a Workable Component of a Functional Regime on ABS

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The concept of a certificate of legal provenance (CLP)[2] has undergone a major evolution over the past 10 years. The newer extended versions of the certificate concept – which proposed comprehensive 'international tracking' systems – raise many expenses and uncertainties. For this reason, it is useful to re-consider the original proposals, which were simpler solutions – 'international registration' systems. Initially, the CLP was conceived as a simple, elegant tool. It created both a registration system and an incentive to use that system:

- For the provider country, the system could:
  - provide an increase in the user's desire and to comply fully with national ABS requirements, setting appropriate measurable standards for 'registerable compliance', and
  - create a legal basis for future oversight and enforcement in both user and provider countries.
- For the user, the CLP could provide several benefits:
  - streamlining their ability to get certain approvals; and
  - especially providing a measurable basis for recognizing 'good' (compliant) users (helping the provider country and providers to recognize the importance of directed strongest enforcement against those who do not make efforts to comply with ABS - true "biopirates").

This is a voluntary exchange. A certificate of legal provenance (CLP) would give the user 'legal certainty' —that is, protection against a later claim that he did not obtain relevant legal permissions. In exchange for this certainty, the user would rigorously comply with requirements and processes necessary to get the certificate.

The underlying mandates compelling use of the 'registration-type' system are clearer than those under the tracing proposals. It is not enough simply to agree on forms and documentation. Those documents will not be used, unless the user is motivated to do so. A certification system can be developed **only** in the context of new law:

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[1] This paper presents the views and 'expert input' of the author only. It does not, in any way, represent the views or policy of IUCN, its members, commissions, or secretariat.

[2] Originally called a "certificate of origin," and promoted in the late 1990s by, inter alia, Jose-Carlos Fernandez-Ugalde and Brendan Tobin.

- User countries must adopt legislation requiring proof of a legal source/provenance, upon commercialization (including patenting, but also other commercialization processes) of products that incorporate (or were created by using) GR; and
- Source countries must adopt laws that (i) cover the issuance and contents of the certificate, and the specific minimum standards[3] that will be used to by the certificate issuer, and (ii) provide that, the country will support properly issued CLPs against challenges based on PIC and the validity of MAT (but not excusing violation of the MAT).

Third, registration-type systems need not to trace all movements of biological materials. A tracing-type (comprehensive tracking) certification system would have to track all biological materials, because all biological materials contain the "functional units of heredity." It will always be possible to extract genetic material from any biological material. Hence, even if a practical definition of 'genetic resources' is ultimately adopted, a tracing-type system would have to track all movements of any biological specimen, in order to address the chance of GR extraction and use in future. This would be virtually impossible. The adoption of exceptions from a comprehensive tracing-type system would serve as 'loopholes' allowing undocumented movement.

By contrast', in a registration-type certification system the incentive to use the system arises out of governmental action. Specifically if (i) the government requires proof of legal source/provenance prerequisites to marketing, introduction, patenting or other desired activities relating to interim, final or derivative products developed from the genetic resources; or (ii) if the law states that a formally issued certificate constitutes such proof, then the user will have an incentive to acquire a certificate, at some point in the use process (in protecting his rights in new inventions, in product development, at the time of introduction, testing or marketing and at other times).

Unlike bar-coding and other broad scale tracing systems, the original certification concept would create a system that is not very expensive, and could be funded primarily from license fees, since it would not require tracking/coding of quantities of biological specimens. The elegance of this system is that compliance would be largely self-motivated. The user will know that his ultimate commercialization will be simplified if he takes the required actions to obtain a CLP.

If he does not have a CLP, a user will have to 'prove' legal provenance. This may mean that the user must give (and the issuer must adjudicate) evidence showing that resources are either (i) not covered by the CBD,[4] or (ii) legally obtained. Where the original specimen was collected or acquired 'informally' or where it came from a collection that does not maintain CLPs for its specimens, it may be difficult to *prove* this for the specimen. Consequently, users may actually prefer to obtain a certificate from a source country, instead of the uncertainties of using insufficiently documented specimens from *ex situ* collections.

Over time, the CLP tool can be tied to other systemic incentives – they may be required in applications to commercialize the product in other countries, for example. It may also be possible to tie the CLP to eligibility for tax benefits for R&D or for other legal benefits to users of GR. This could enhance the preference for resources obtained from developing countries over those obtained from *ex situ* collections or other sources.

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[3] Developing these standards is not a simple matter. However, it may be much simpler than addressing some of the problems identified in the discussion of current "international tracking system" proposals.

[4] See Article 15.3, removing from Article 15, certain (essentially pre-convention) specimens.

Final Point

It is important to decide exactly what the certificate is supposed to do, before attempting to develop it. CITES provides a useful example of how a certificate can be developed in international law. The specific provisions of CITES set forth both general and specific objectives, on the basis of which they describe a comprehensive certificate system designed to implement it. Even with such a process:

- CITES permits and certificates have been 'adapted' by many Member Countries (so are not entirely uniform); and the Convention is
- still being refined and adjusted by the CITES COPs to enable it not only to better suit its specific objectives but also to help the system to more effectively promote its long term objectives.

Conclusion

Certainly, the broader 'international tracking system' approach gives some satisfaction at a conceptual level. It is important not to overburden the concept, or try to use it to solve all of the problems of ABS. A more simplified, incentive based CLP system may be a quicker and more effective tool of enabling ABS.

B. Certification systems: Company Conduct, Standars and Certification

ABS Management Tool Project: Summary Project Description

Jorge Cabrera. Legal Adviser, Instituto Nacional de Biodiversidad (INBio), Costa Rica. E-mail: jacmed@racsa.co.cr **George Greene.** President, Stratos Inc., Canada. E-mail: ggreene@stratos-sts.com **Tom Rotherham**. International Institute for Sustainable Development (IISD). Email: trotherham@iisd.org

Article 15 of the Convention —entitled "Access to Genetic Resources"— reiterates the sovereign right of States over their natural resources and declares national governments to have the sole authority to determine access to genetic resources. The Article states the general principles on which access is to be granted, namely mutually agreed terms and prior informed consent. It also requires that Parties to the Convention take measures for the sharing of benefits from the use of genetic resources with the Party providing such resources.

The first concrete work undertaken to implement Article 15 of the CBD resulted in the adoption, in 2002, of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, referred to as the *Bonn Guidelines*. The Bonn Guidelines are a voluntary set of provisions designed to help countries implement in their own jurisdictions the sections of the CBD relating to access and benefit-sharing (ABS).

However, the Bonn Guidelines are directed to all actors involved in ABS-related activities and so do not, in all cases, give guidance that is easy for specific user or provider organizations to interpret and implement. In particular, non-State users and providers, including research organizations, private companies, communities and indigenous peoples' groups, have a need for clear guidance and tools to help them understand and implement the CBD's provisions on ABS, including in particular the Bonn Guidelines.

The ABS Management Tool Project takes a first step towards filling this gap. The ABS Management Tool Project Report, along with an accompanying background research report, are the first substantive outputs of a project funded by the Swiss Government. The Project Report contains both an overview of the objectives, management and activities of the project, as well as what is referred to as the Working Draft ABS Management Tool — a set of performance standards and process recommendations designed both to help clarify good ABS practice and to guide its implementation.

The Working Draft Management Tool comprises two components:

- *ABS Practice Standards*. Addressing seven key elements of ABS: prior informed consent; mutually-agreed terms; benefit sharing; conservation and sustainable use; traditional knowledge, innovations and practices associated with genetic resources; community and indigenous peoples participation, and, information and transparency.
- *A Management Process Framework*. Including process guidance on development of an ABS Policy Statement; decision-making on relevant ABS practice standards; implementation steps including objectives, monitoring and consideration of internal assurance; identification and tracking of genetic resources; responsibilities and accountabilities; and, resource requirements.

This piece summarizes the output of Phase 1 of the project. A second phase is underway to run from September 2004 until December 2006, during which the Working Draft ABS Management Tool will be disseminated for broad public input and field-testing, and then revised based on public comments and experience with regards its use.

The final output of this three-year project will be an ABS Management Tool that guides users in their practices for seeking access to genetic resources and providers of genetic resources in their decisions about granting access; and, to providers and users in the negotiation of agreements and their implementation and monitoring. The tool is intended to be applicable for all relevant stages of use of genetic resources. It is designed to help bring consistency to the planning and implementation of ABS activities. In so doing, the project will also build awareness of the Bonn Guidelines, lend confidence to those involved in ABS activities, facilitate access and benefit-sharing, and promote a better understanding of what works and what does not in the promotion of good ABS practices.

For additional and current information on the ABS Management Tool Project:

Web site: www.iisd.org/standards/abs.asp

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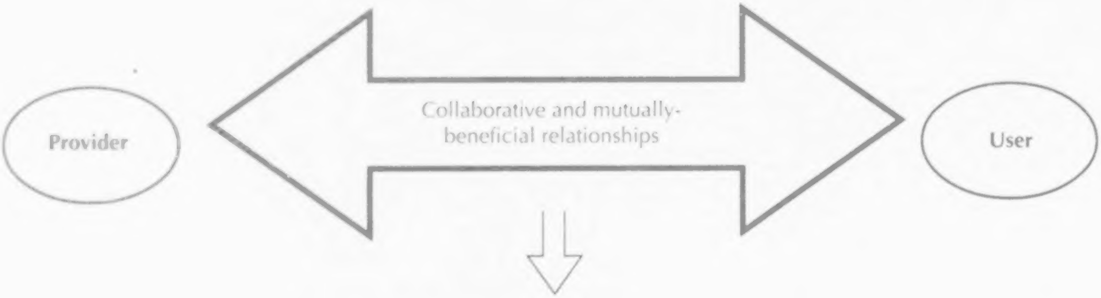
The following summarizes the Working Draft Management Tool.

Working Draft ABS Management Tool

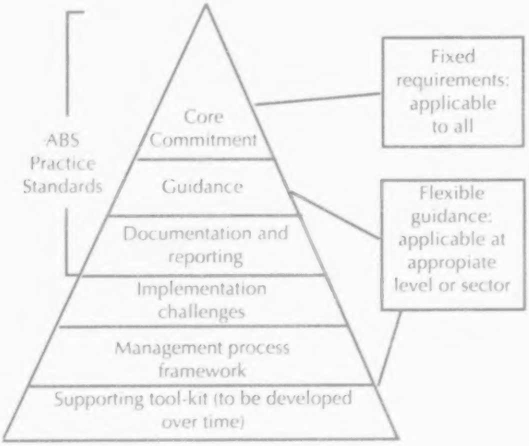
The management tool is for the use of ABS practitioners and ABS policy-makers. It is targeted, for internal management purposes, to individual organizations wanting to voluntarily adopt good practices in accessing genetic resources and in providing fair and equitable benefits from their use, and that are prepared to demonstrate such good practices. It will also guide compliance with existing ABS laws, policies and regulations, and will help inform ABS regulators with important steps and practices.

It is designed to give practical guidance to users of genetic resources in seeking access in a manner which fully respects the CBD. It can help providers of genetic resources in making decisions about access, by increasing the understanding of what they can expect and what conditions they may request in granting access. It is useful to both providers and users in the negotiation of agreements and their implementation and monitoring.

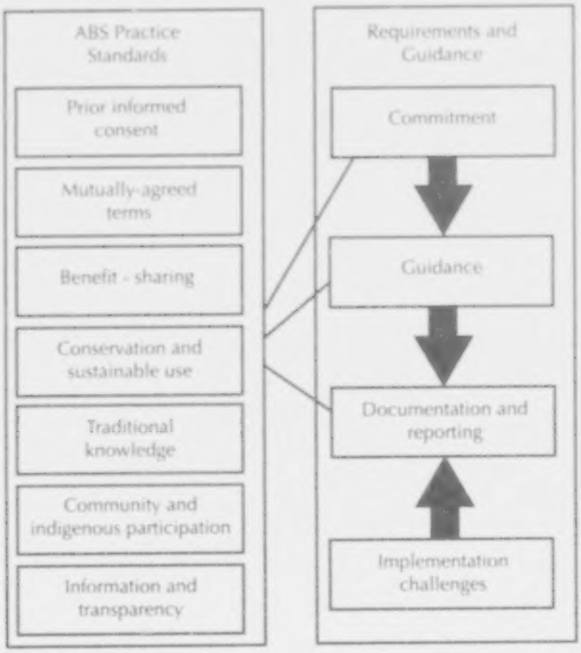

Provider
Collaborative and mutually-beneficial relationships
User

Build Confidence to interact
Provide information to inform negotiation
and decision-making
Engender trust to work together

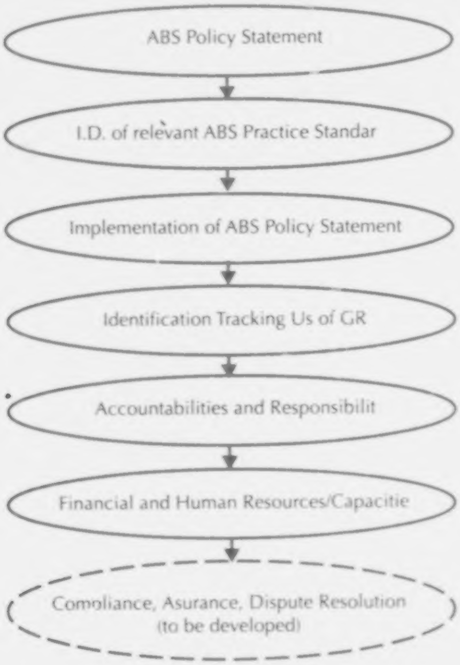
Structure of the ABS Management Tool


ABS Practice Standards
Core Commitment
Guidance
Documentation and reporting
Implementation challenges
Management process framework
Supporting tool-kit (to be developed over time)
Fixed requirements: applicable to all
Flexible guidance: applicable at appropiate level or sector

ABS Practice Standards


ABS Practice Standards
Prior informed consent
Mutually-agreed terms
Benefit - sharing
Conservation and sustainable use
Traditional knowledge
Community and indigenous participation
Information and transparency
Requirements and Guidance
Commitment
Guidance
Documentation and reporting
Implementation challenges

Key Elements of the Management Process Framework


ABS Policy Statement
I.D. of relevant ABS Practice Standar
Implementation of ABS Policy Statement
Identification Tracking Us of GR
Accountabilities and Responsibilit
Financial and Human Resources/Capacitie
Compliance, Asurance, Dispute Resolution (to be developed)

ABS Practice Standards Core Commitments

ABS Practice Standard 1 Prior informed consent (PIC)

Core commitment:

- PIC is prior, informed and consented in intent and practice;
- Prior informed consent is obtained in writing from the competent government authority, and from the relevant stakeholders, including local communities and indigenous peoples;
- Prior informed consent is linked to a commitment to negotiate fair and equitable benefits for each stage of access and use. Genetic resources are used only for the purposes expressly outlined at the time of PIC negotiation, and a new prior informed consent is given for any use that differs in type or scope from that originally outlined;
- Prior informed consent is linked to mutually-agreed terms and benefit sharing; and
- Where access is obtained from an *ex situ* collection including from one or more intermediary, documentation should be provided that appropriate PIC exists, and that the transaction and intended use are consistent with that PIC, unless there is clear and reasonable explanation that this is not feasible.

ABS Practice Standard 2 Mutually-agreed terms (MAT)

Core commitment:

- Mutually-agreed terms are negotiated in a manner that builds confidence and a relationship of trust between owners, managers or custodians of genetic resources who are the providers and the users of genetic resources, and which establishes the basis for a long-term, transparent and respectful relationship and communication between them;
- MAT is negotiated in good faith by both users and providers, respecting the terms and understandings of prior informed consent, allowing benefits to flow to the owners, managers or custodians of the genetic resource, and facilitating access; and
- Mutually-agreed terms take into account the differences in capacities and needs of the providers, including governments, indigenous and local communities, holders of *ex situ* collections, and the intended user organizations to allow fair processes of negotiation and equitable outcomes in the benefits to be shared.

ABS Practice Standard 3 Benefit Sharing

Core commitment:

- A fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge is provided to support the compliance with the three objectives of the Convention on Biological Diversity;
- Benefits are provided according to the specific stages of use set out in the PIC agreement (discovery, research, development and commercialization) and are renegotiated when the type of use is expected to change beyond the agreed PIC;
- Benefits are shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific or commercial process, including governments at different levels, and/or indigenous and local communities and relevant stakeholders that are the owners, managers or custodians of the genetic resource; and
- Benefit Sharing arrangements are implemented in good faith, respecting the terms and understandings of prior informed consent agreed for use of the genetic resources collected, and the terms and conditions negotiated in the mutually-agreed terms.

ABS Practice Standard 4 Conservation and sustainable use

Core commitment:

- The collection and/or harvest of wild genetic resources is conducted, using a precautionary approach, at a scale and rate and in a manner that does not exceed the sustainable yield and that does not impair ecosystem structure, functions and services;
- Domestication and cultivation/captive breeding of genetic resources is conducted in a manner that maintains the genetic variation of the population or diversity of the gene pool;
- Species listed in CITES Appendix 1 and species considered to be globally or locally threatened according to the IUCN Red List or equivalent categories are not collected, except for the purpose of species conservation research. No collection is undertaken in legally-established protected areas that prohibit collection; and
- Knowledge about biodiversity that arises from access to a genetic resource is shared in a manner that supports and enhances conservation management.

ABS Practice Standard 5 Traditional knowledge, innovations and practices associated with genetic resources

Core commitment:

- The integrity of the traditional knowledge associated with genetic resources that are accessed is respected by the collector of genetic resources and other users. The collection and use of TK is made in such a way as to not affect the integrity, sense and value of the TK, so as to not denigrate it;
- Fair and reasonable effort is made to preserve, respect and maintain traditional knowledge associated with the genetic resources that are accessed; and
- Adequate compensation and sharing of benefits are provided when traditional knowledge associated with genetic resources is accessed and used.

ABS Practice Standard 6 Community and indigenous peoples participation

Core commitment:

- Effective communication, transparency and consultation is maintained between intended and actual users and the providers of genetic resources —governments, indigenous and local communities, and relevant stakeholders, including their involvement in the granting of PIC and negotiation of MAT;
- The specific concerns and interests of stakeholders, including local communities and indigenous peoples, are responded to through information on intended action —either in the form of commitment to resolve or rationale for why action is not taken, and
- Indigenous and local communities that are owners, managers or custodians of genetic resources, and relevant stakeholders, are involved in decision-making on access and participate directly in benefits derived from collection and use of genetic resources.

ABS Practice Standard 7 Information and transparency

Core commitment:

- Information related to the genetic resources under consideration, including intended use, is shared in a transparent and open manner between potential providers and potential users of genetic resources —in line with the appropriate stage of negotiation and agreement;
- The quantity and quality of information available and provided is sufficient to enable the genetic resource provider and the intended user of the genetic resource to make informed judgments and decisions, and to undertake actions to implement all agreements reached between the provider and the user;
- The confidentiality needs of commercial interests and holders of traditional knowledge are maintained, while working to the spirit of transparency in ABS relationships, and
- Where applicable, traditional and local knowledge is protected in the process of access and not made widely available without the consent of local or indigenous communities.

Tropical Biodiversity: An Industrial Perspective

Lene Lange. Microbial Discovery, Novozymes A/S. E-mail: lla@novozymes.com

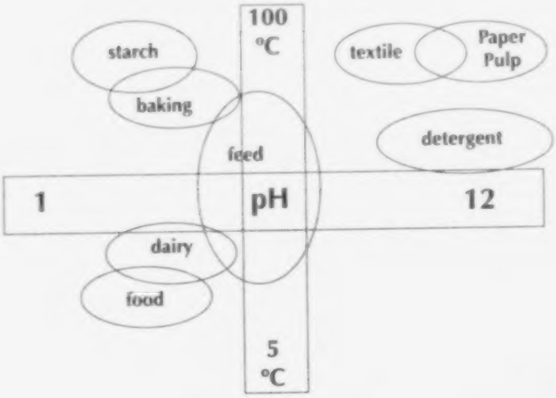
Introduction

When Novozymes de-merged from Novo Nordisk in 2001, we made "Unlocking the magic of nature" the basis for our branding. In 2004, we, more than ever, imagine a future where biological solutions create the necessary balance between a cleaner environment, better lives and better business. For such a vision of global sustainable development, further investigation and exploitation of biological kingdoms and biochemical diversity is both an integrated and necessary ingredient. This vision makes room to allow such progress, based on fair and equitable benefit-sharing, making it a win/win situation for all parties, technologically as well as financially.

The Importance of Biodiversity

Novozymes is a biotech-based world leader in enzymes, with a market share of approximately 44% for technical enzymes. We have all types of industrial enzymes and enzymes for feed and for food in our product portfolio. Such industrial sectors and applications include a very wide range of process conditions. These conditions, relating temperature and ph level to the product segment in question, is pictured in Fig.1. This figure shows how apparent it is that we will need to access natures' biodiversity using a very broad approach, ecologically as well as phylogenetically, to optimize the chances of finding the enzyme which is best for each of the different applications. Article 15 of the Convention on Biological Diversity (CBD), entitled "Access to Genetic Resources", reiterates the sovereign right of states over their natural resources and declares national governments to

Figura 1. Process conditions for Industrial Applications.



have the authority for determining access to genetic resources. The Article states the general principles on which access is to be granted, namely mutually agreed terms and prior informed consent. It also requires Parties to the Convention to take measures for sharing the benefits from the use of genetic resources with the Party providing such resources.

The Value of Tropical Biodiversity

Clearly, tropical biodiversity is certainly rich from a species point of view, but additional factors make access to biological resources originating from the tropics of special interest. In brief, four of these factors are: (i) the tropics hold a series of special extreme and interesting ecological niches (salt lakes, deserts, caves etc); (ii) they also have a wealth of microbial diversity - specifically associated endemic species, flora (epiphytes, endophytes and pathogens) and fauna (e.g. insects pathogens and endosymbionts); (iii) special taxonomic and biological expertise and collections are being built up in the tropics, e.g. the BIOTEC, Thailand collection of insect pathogenic fungi (based on the expertise of Nigel Hywel Jones) and (iv) tropical natural resources have been studied and used for centuries, with indigenous knowledge extensive. This last factor has attracted interest from several drug screening industries. Novozymes interests, however, are primarily centered around enzyme discovery and not on indigenous knowledge.

Enzyme Discovery

Molecular studies of biodiversity have focused on a few genes, such as 16S, 18S, 28S, ITS, as well as a few household genes, such as beta-tubulin. Such genes provide the basis for phylogenetic concepts, groupings and classifications. However, enzyme genes have only been studied to a limited extent in a comparative way. The preliminary results show that when a comparative functional genomics approach is taken to fungal enzyme genes a quite different picture appears. Here it becomes evident that gene diversity can be obtained just as much by approaching different ecological niches as by ensuring a broad phylogenetical representation during the screening. Put another way, good industrial performers for any given application may be found by studying all types of organisms in a given physiological niche as well as studying species around a taxonomic hot spot. This gives weight to the importance of studying unique ecological niches —among those, the ones found in the tropics.

International Treaties

In order for a company to have access to such biological material, and be in compliance with international charters, a whole set of precautions, practices and principles must be taken into account. First of all, the word and spirit of the Convention on Biological Diversity (CBD). However, a number of other international treaties are also of importance:

- Quarantine regulations
- Convention on Biological Diversity, Rio (1992/1994)
- Biosafety Protocol, Cartegena & Montreal
- FAO International Treaty (2001/2004)
- Bonn Declaration on Access and Benefit-sharing (ABS)

The last of these, the ABS Bonn Declaration, tries in many ways to put a number of the stated previosuly into action, and which we as industry have tried to use as part of our effort to comply fully with the CBD. The Novo Guiding Principles for access and benefit-sharing was formulated and published in the Novo Nordisk 1997 Annual Report.

Successful CBD Experience

An example of a productive and well functioning biodiversity research collaboration between BIOTEC, Bangkok and Novozymes is given in Fig 5.

CBD Pitfalls

Experience from many years of discussing how to make CBD collaboration work, and giving results and benefits for all parties involved, have revealed a number of obstacles that often get in the way of a fruitful result. Five of the most important of these are highlighted below:

- *Mismatch of expectations!* The providing country negotiator may not be fully aware of the full investment required to bring a new and interesting organism, gene or active compound to the level of commercialization. Further, the provider may not know the differences between the profit margin of different industries; that e.g. the industrial sector has a significantly lower profit margin that the pharmaceutical industry and that even royalties as high as 5% or 10% cannot guarantee commercialization. In this sector, 0.5 to 1 or 2 % royalties for finding and providing the gene product is more likely to be the outcome.
- *Middle men benefit!* The CBD was created and internationally agreed upon in order to ensure that the provider countries of biological resources received a fair share of the benefits based on their use. Within international collaborations, many types of players take part in access and transfer. An important role is played by international culture collections. Without their activities and skilful interventions a lot less would be known about biodiversity in the tropics and a lot less would be available for researchers (both commercial and academic) around the world. However, the over arching purpose of the CBD should still be kept in mind, with benefit-sharing centred in the country from where the biological material was sourced. The middle men should be paid for their efforts and have expenditures compensated, but they should not receive royalties from possible product commercialization.
- *Difficulties in getting prior informed consent (PIC).* Responsible companies do not access and transfer biodiversity resources of a given country without having ensured that everything is in compliance with the CBD. In order to be in compliance, the most important step is to obtain prior informed consent (PIC) from the proper authority in the provider country. Many countries have not established such procedures. This means that industries will have to choose their countries of CBD collaboration not only based upon where the most interesting biodiversity is located but also where PIC procedure and the CBD legislation are in place. This reality highlights the unfairness of the world we live in: whereby countries with the lowest level of development and the least educated population may not be chosen for such CBD collaborations because of these very limitations. As such, extra value generated from their biodiversity may not be an option for the poorest countries.
- *Obstacles for scientist/scientist collaboration.* Many countries have worked out procedures for obtaining PIC only from a governmental point of view. The opposite procedure —implementing guidelines to aid scientists in the tropics to find a way to get PIC for a research collaboration, involving access and transfer of biological materials— is often very difficult to develop. This is a shame as it is often this type of collaboration where the best chances for technology transfer exist. It is worth noting that most biological resources to be studied will not lead to any commercial product. The best way of ensuring that the providing country does benefit from a CBD collaboration, even if no commercial product is being developed, is to agree that industry includes specific resources in their screening for sharing results, capacity building and technology transfer. Such collaborations will eventually enable biodiversity-rich countries to be able to exploit their own biological resources.

- *Academia not in compliance with the CBD*. Many university groups do continue with normal practices when dealing with access of biological resources, especially in the tropics. There is a general belief that if you are from a university with a non-commercial, purely academic research purpose you may not need to have PIC in place. However, serious problems may occur when university groups stumble upon interesting findings and approach industries for possible exploitation and development. In such cases, industry has to ask questions such as: Was PIC obtained from the proper authority? If not, the industry cannot go on and utilize the finding. However, too much bureaucracy may also be hampering academic investigations which potentially could benefit the whole international scientific community. Maybe a new type of PIC should be devised for academic purposes only. Even then, an additional procedure to follow if findings are to be channeled forward for commercial purpose studies must be put in place.

CBD, Culture Collections and Industry!

The scientific community operates with many types of information sharing and transfer:

- Scientific publications. All material published is placed in the public domain and the information can be freely used by all parties.
- Patents. All information in patents can be used to make new discoveries and new inventions.
- Gene sequences, deposited in public gene data bases can be freely used as input for further research, academic as well as for commercial purposes.
- Specimens from collections in botanical gardens and herbaria are exchanged by internationally agreed rules. Only the possible isolation of microbes living on such plants represent a grey area - not currently under regulatation. Are they part of the biodiversity of the country of the botanical garden? or. Does the microbe belong to the country where the plant was originally found?
- The International Culture Collections' implementation of the CBD is still under discussion. The Novozymes suggestion for Rules of Conduct is based on the following analytical approach: International culture collections are part of the international scientific community and contribute to the advancement of science. Both industrial and developing countries benefit from the taxonomic, culturing/preservation, and curator work done by culture collections. When you deposit a culture in a culture collection you benefit from a state of art depository and also, by offering the cultures for sale, you place it in the public domain. This helps gives industry, as well as academia, a possibility to access, transfer and evaluate the strains. However, if something of commercial potential is being developed, the country of origin should receive benefit-sharing in a fair and equitable way, in full accordance with the CBD.
- When biological resources are accessed and transferred directly from a tropical country, full CBD compliance, including prior informed consent and mutually agreed terms, must be obtained prior to any access. The difference when compared to access of strains in culture collections is that when industry uses strains from such collections they can be screened without having CBD compliance in place, while accessing resources directly from a provider country must have the full paper work and agreements in place.

As listed above, the different forms of access can be placed in a spectrum, ranging from being totally in the public domain to the most restricted CBD procedures for transfer of biological materials. The examples above are placed in increasing order, correlated with increasing restrictions in what it takes to access and use biological resources.

Conclusions and Recommendations

A principle for the industrial use of strains from international culture collections is proposed based on an analytical approach of various types of knowledge sharing and transfer. This principle states that purchased culture collection strains can be freely included in industrial screenings although the findings can only be entered into a commercialization phase when agreement regarding CBD compliance has been reached. The establishment of an international fund for such compensations should be considered.

It is further recommended that industry access to biological resources carried out in the tropics be done, as a general rule, through collaboration with local scientists. As part of such collaborations, duplicate strains of all strains to be transferred should be left in the country of origin under proper conditions for preservation.

A code of conduct for obtaining prior informed consent under mutually agreed terms should be worked out to ease and mediate further collaboration between scientists working in the tropics and industrial scientists. Such collaboration could be conducive for the development of more biological solutions and the generation of greater revenues based on biodiversity resources.

Such a code of conduct should act as a guiding principle, and be split into two parts: the screening phase, where the industry gets an option to include strains from the tropics in their search for new products. The benefits from this phase for the providing country should include capacity building and technology transfer. The second phase is the commercial development and the commercialization phase. Here monetary benefits, as up-front lump sums or royalties for the providing country, are based on actual income for the industry.

DISCUSSION PAPER

Company Conduct, Standards and Certification

Peigi Wilson, LL.B., Director, Environmental Stewardship, Assembly of First Nations, E-mail: pwilson@afn.ca

It must be taken as given that it is to the advantage of the business sector to work cooperatively with First Nations. This paper will consider how corporations can engage indigenous peoples in developing certification systems or industry standards for access and benefit-sharing agreements. I will speak about the circumstances in Canada only. There may or may not be similarities with the situation in Canada for indigenous peoples elsewhere in the world. Please note I am not an expert on these matters. I can only speak from my personal experience.

The First Nations in Canada are wary of those interested in doing business in their territories. They have suffered tremendous privations as a result of 400 years of colonialism and are only now beginning to recover. Newcomers, with brash promises of the good life, seeking access to First Nations lands and resources are not a new phenomena. Sometimes, the newcomers do indeed bring prosperity, but more often they have brought disease, drugs and alcohol, leading to community disruption and disharmony. Any benefits, if they were in fact realized, were often short lived. The boom and bust cycle of resource development is not new. First Nations have, as a result, grown cautious in their dealings with the non-aboriginal world.

They have also become increasingly sophisticated in their dealings. Many First Nations people are quite comfortable in the board room, court room, or at the negotiation table. While there are wide disparities of capacity among First Nations communities, industry should expect to find highly capable individuals involved at the community level working to secure the interests of the nation.

It should be noted that there is great variety between First Nations. There are approximately 50 nations in Canada, represented by over 630 communities, each with their own Chief and Band Council or other governing body. There are different languages, customs and taboos. This makes for tremendous diversity. Working with one community to develop standards or compliance systems does not guarantee that another community will accept the same approaches. This is important to remember. No business person would expect to do business in Japan the same way business would be conducted in China. Learning the culture of the community with which one expects to do business is often critical to the success of the venture.

In Canada, First Nations have been successful in negotiating treaties with the federal and provincial or territorial governments for land and self-government. Lands subject to land claim agreements include over 2,000 square kilometres held by the Nisga'a, 14,000 square kilometres held by the James Bay Northern Quebec Cree as Category 1 lands (lands over which they have exclusive authority), 41,000 square kilometres for the Yukon First Nations and 1.9 million square kilometres for the Inuit under the Nunavut Land Claims Agreement. There are also a significant number of outstanding claims by First Nations and Métis in Canada, including claims for most of the province of British Columbia and the Atlantic Provinces of Nova Scotia, New Brunswick and Prince Edward Island. These land claim agreements may include exclusive jurisdiction over tens of thousands of kilometers, including genetic resources in those territories. Under self government agreements protected by the Constitution of Canada, First Nations may have their own courts, enforcement officials, and consultation policies. As constitutionally protected treaties, they form part of the highest law of the land and cannot be legally amended without agreement of all parties to the agreements, including the First Nations.

What this means for the business world, is that First Nations are a significant player in the search for genetic resources and associated traditional knowledge. This also means that First Nations are not "stakeholders". They have rights beyond those available to others in Canada. This includes rights superior to business interests and different from rights of non-aboriginal people in Canada. First Nations are a third order of government in Canada and must be considered from this perspective when business chooses to engage in activities that have the potential to impact First Nations' interests.

How then can First Nations be involved in this work? There are myriad cultures, laws, capacity levels, and interests to consider. How can business be sure that they are following appropriate procedures, that they can get requisite decisions, and that they are talking to the right people? The best answer I can provide is to encourage business to work directly with the affected First Nation, approach the community with respect, expect to take time to build personal relationships, and allow adequate time for decision making at the community level.

There are certain protocols that should be respected in approaching First Nations. Firstly, it is correct to approach the community to ask for permission to work with the community on a particular matter. Sometimes this will involve a presentation to the Band Council or other governing body, to the Elders, or to the community as a whole. In some communities there are clearly defined processes and terms for considering business proposals. In others one will have to feel one's way through the process as there is no written code of conduct. Note that the decision making process may well be closed to the public.

The community will likely take time to study the invitation to become involved and will likely not appreciate demands to move quickly. Be sure to build in time for broad and lengthy community discussion. There is a great deal of distrust to overcome and so people are unlikely to make quick decisions until they have considered the issue from many angles. In addition, there are elements of the decision that the First Nations will likely consider that may not be common to non-aboriginal peoples' perspective on an issue. For example, First Nations will likely take into account the long-term consequences of any request for access and consider the impact seven generations hence as well as the impact on the non-human world. There is a very strong sense of responsibility to the non-human world that will likely be factored into the decision.

Indigenous peoples will be more inclined to permit access where they see respect for their laws and customs and benefits to their communities arising from such access. As a general rule, industry should work to involve indigenous peoples, incorporate indigenous perspectives, and establish inclusive structures. It may be challenging to work with First Nations, but doing so will generally result in more satisfactory arrangements, greater trust and therefore long term project stability.

C. Measures and Compliance Mechanisms for key Actors; Government uses Measures - Incentives for Compliance

Government User Measures - Incentives for Compliance

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Measures to Support Compliance with the CBD and Prior Informed Consent

There is a range of measures that countries —particularly developed countries— could take in their role as users of genetic resources. This paper will provide examples of user country measures taken in Norwegian patent legislation.

Norway has recently amended the national patent law to support compliance with the CBD and prior informed consent (PIC) of the Country of Origin/Contracting Party providing the resources.[1] The amended law applies to patent applications submitted from 1st February 2004 when the law entered into force.

Some of the reasons behind these amendments were that disclosure requirements will increase transparency and make it easier to verify:

- Whether the genetic material is acquired in accordance with the CBD and/or national legislation in the Country of origin/providing country;
- Whether the conditions for patentability exist, and
- Whether the patent application concerns an invention that is already known (prior art) for example with regard to traditional knowledge.

The amended Patent Law, new para. 8b reads as follows:

> If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent (PIC), the application shall inform on whether such consent has been obtained.
>
> If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from *in situ* sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall provide information on that.

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[1] The amendments of the Patent Law were also made as a follow-up to incorporation of the Directive 98/44/EC on the legal protection of biotechnological inventions into the EEA agreement (Agreement on the European Economic Area)

The duty to provide information under the first and second subsections applies even if the inventor has altered the structure of the received material. The duty to provide information does not apply to biological material derived from the human body.

It should be added that the requirement to disclose PIC does not require that documentary evidence of PIC is supplied with the patent application. It is sufficient to state in accompanying documentation that PIC has been acquired in accordance with the national legislation of the Country of Origin/ Providing Country. In addition to support compliance with PIC (if required by national law in the Country of origin/providing country), it will also contribute to awareness raising with regard to the CBD provisions amongst patent applicants.

Penalties in cases of infringement of the duty to disclose information lies outside the patent law, namely in the General Penal Code § 166. This paragraph states that:

> Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.
>
> The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases.
>
> The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents.

When the law was first proposed to the Norwegian Parliament, a minority argued to include an additional disclosure requirement in patent applications. If this had been accepted it would have required the patent applicant to disclose whether mutually agreed terms on benefit-sharing exist with the country of origin/providing country of genetic resources.

The information requirements are not applicable to international patent applications submitted through the Patent Cooperation Treaty system, as this would be contrary to the obligations pursuant to the Patent Cooperation Treaty.

Consequently, Norway wants to contribute to finding a multilateral approach to the issue of disclosure and has proposed that the IGC-committee recommends to the member states of WIPO to amend the PCT convention, and thereby enable the use of disclosure of origin in the processing of patent applications in the national phase. A multilateral approach to the issue of disclosure would create a level playing field for all patent applications.

Norway welcomes and supports the Swiss proposal on Rule 51bis tabled in the Working Group on Reform of the Patent Cooperation Treaty. The proposal to amend the PCT would explicitly allow the Contracting Parties to require an international patent application to contain a reference to the origin of genetic resources.

To illustrate the importance of the Swiss proposal: in 2002, 70% of all patent applications in Norway were applications under the PCT. Of the remaining 30%, only a few applications concerned biotechnological inventions. Norway therefore looks forward to further discussions in WIPO on this and other proposals with a view to an agreement on how the PCT may be amended to meet the concerns related to the CBD.

Moreover, in the framework of the TRIPs Council on the relationship between the TRIPs agreement and the CBD, Norway has argued that a provision could be inserted into the TRIPS agreement that would either *require* or *enable* members to oblige a patent applicant to disclose the source of origin of biological material which forms part of an invention. Such a failure of revelation would not result in the rejection of the patent. It is important to underline that from a *legal* point of view, nothing in the TRIPS agreement today prevents a member from requiring patent applicants to disclose such information, provided that a failure to reveal the origin of the material would not in itself result in the rejection of the patent.

Other Measures

In the preparatory work for the amendments of the patent law[2] there is a reference to the CBD provisions which establish obligations for countries to take measures "with the aim of sharing in a fair and equitable way *the results of research and development* and the benefits arising out from the commercial and other utilisation of genetic resources with the contracting Party providing the resources" (Art. 15(7)).

The CBD is not only limited to dealing with the use of genetic resources through the patent system. Other uses of genetic material, such as research and development activities which have not reached the stage of an invention to be patented, also need to be dealt with. It was concluded in the preparatory work that a large part of measures to implement the CBD objectives has to be taken outside the patent system.

The Norwegian government appointed in April 2001 an expert committee assigned to examine Norwegian legislation with the aim to strengthen legal measures for the protection of biodiversity in Norway, including how legislation responds to issues within the scope of the CBD and other relevant international instruments.

Access to genetic resources and benefit-sharing are identified as separate and priority issues in the mandate of the Committee since this is an area not yet subject to legislation in Norway. International instruments such as the Bonn Guidelines have been used as input to this work. Norway is considered as both a provider and user country of genetic resources, and therefore the mandate is to propose legislation both with regard to access to genetic resources in Norway and regulations concerning the use of genetic resources originating from other countries but used in Norway.

The committee will submit its report and legislative proposal by the end of 2004.

Another government committee has been assigned to revise the law on marine resources. This will include new proposals in relation to access to marine genetic resources and marine bioprospecting. This committee will submit its report by mid 2005.

The Nordic Genetic Resources Council has also conducted a work on access to genetic resources and benefit-sharing, which resulted in a Nordic Ministerial Declaration (Nordic ministers for agriculture, forestry, fish, food and the environment) in 2003.

The respective Councils of ministers approved a declaration which established principles and objectives for how the Nordic countries should deal with the issues of access and rights to genetic resources.[3] It was, in particular, emphasized that the Nordic countries as users of genetic resources should take steps to help provider countries of genetic resources to comply with access legislation.

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[2] Proposition to the Odelsting 86(2002-03)

[3] Ministerial Declaration on Access and Rights to Genetic resources, Norden 2003

Measures with Regard to Respecting Traditional Knowledge (TK)

The interpretation and implementation of the conditions for patentability varies in some cases from country to country with regard to whether the invention is new; whether it represents an inventive step and whether it is susceptible to industrial application.

Traditional knowledge (TK) is often not published in writing due to several reasons, *inter alia* because of tradition to keep such knowledge secret from the public. According to Norwegian law it is sufficient that the TK is made known, to constitute an obstacle to patentability. There are no requirements for written publications in Norwegian legislation when deciding what is prior art, and such knowledge may also be provided orally. There are not any cases yet in Norway where TK has been used as the basis for opposition related to patent applications. This will be considered on a case-by-case basis. Remedies are thus available under patent law to TK holders whose TK has been misused, as far as the knowledge is known.

The issue of respecting traditional knowledge is also a part of consideration in the legislative process on access and benefit-sharing in Norway.

User Measures in Provider Countries: Use of Simplified Procedures and its Trade Implications

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Introduction

Governments have made important efforts to implement the provisions of the Convention on Biological Diversity (CBD) on access and benefit-sharing (ABS). However, it was noted early on that most of attention was being focused on developing regimes to control access and less attention was being paid to developing measures to promote compliance by users. The result was a perceived imbalance in commitment between provider (mainly developing) countries and industrialized countries towards securing implementation of the CBD's ABS objectives. Consequently, measures taken by countries with users within their jurisdiction were seen as a mechanism for redressing the balance between providers and users. Nonetheless, this new focus has momentarily prevented the development of other measures that could also bring a combined and integrated approach.

This short paper explores the adoption, at the national and international level, of user measures taken by provider countries, particularly, the use of simplified procedures for nationals whose jurisdictions have adopted user measures.

These kind of measures could raise important trade concerns which are herein described and briefly analyzed in order to identify limitations and opportunities.

User Measures

The development of user measures may be seen as a means for avoiding the development of restrictive ABS laws in provider countries. User measures have been defined as:

> A package of legal, administrative and policy measures designed to promote compliance by users of genetic resources and traditional knowledge with obligations regarding Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Benefit-Sharing (BS). These measures can be applied by either the private or public sector and may be mandatory or voluntary.[2]

In the Bonn Guidelines, user measures were further elaborated upon and a list some of the possible measures was included. Despite the fact that this list was not exhaustive or limitative, they could easily be commonly understood as the only effective user measures, which is clearly not necessarily the case.

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[2] Scoping Meeting on Capacity Building Approaches for Access to Genetic Resources and Benefit-Sharing. UNEP/CBD/ABS/EW-CB/1/INF/1, Appendix II, paragraph 2.

The development of user measures in provider countries covers an apparent gap in the ongoing discussions of these measures. A recent study (Barber and Tobin 2003) on user measures noted that:

> This study is based on the premise that user measures should at first instance be adopted primarily by countries with extensive biotechnology... activities in their jurisdictions. The... adoption of user measure regimes in countries with little... industrial biotechnological capacity... may be questioned and will need to be considered in more depth in future analysis of these issues. (Barber and Tobin 2003, p.18).

A proposal in this regard may have been one suggested by Tully (2003):

> Relevant to compliance with trade commitments, States may elect to restrict access on non-parties nationals on the basis that access is one of the interwoven reciprocal obligations created by the CBD (Tully 2003, p.96).

As mentioned previously, the proposal attempts to introduce the use of simplified procedures for ABS and only make them available for nationals whose jurisdictions have adopted user measures. The measures would fully recognize efforts in other jurisdictions, which may be needed in order to bring balance again to the global ABS system.

The call from the World Summit on Sustainable Development to develop an international regime provides further impetus for investigating and implementing user measures as the regime would need to be a cooperative enterprise.

Description of the Measures

The measures would consist of introducing, at the national level and as part of the international regime, a provision that provides[3] simplified procedures for nationals of jurisdictions where user measures have been adopted.

The identification of such user measures could be realized through a database administered by the Secretariat of the CBD (or another body with a similar role) and built upon the information provided by National Competent Authorities. The decision to be entitled to apply for simplified procedures could be taken at the national level by the National Competent Authority where access is going to take place.

The type of user measures that would trigger the simplified mechanism could be listed in the national legislation in order to provide certainty. In addition to the user measures, which the Bonn Guidelines have already identified —including disclosure requirements and the use of certificates— there are also some relevant provisions of the CBD in this regard. These are provisions that do not focus on rights to control access (Barber and Tobin 2003) but rather on an obligation to take:

- Measures adopted with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the contracting Party providing such resources (Article 15(7));

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[3] It must be evaluated whether it should be an *obligation* or a *right*.

- Measures with the aim of ensuring that countries providing genetic resources are provided access to and transfer of technology, which makes use of those resources (Article 16(3));
- Measures to facilitate access and transfer of technologies relevant for conservation and sustainable use of biological diversity or which make use of genetic resources, including measures with the aim that the private sector facilitates access to joint development and transfer of such technologies (Article 16(1) and (4));
- Measures to provide for effective participation in biotechnological research activities by countries providing genetic resources, where feasible in the providing country (Article 19(1)), and
- Priority access to be provided to developing countries on a fair and equitable basis to the results and benefits arising from biotechnologies based upon genetic resources provided by them.

The rationale behind these measures would be two fold. First, by introducing the measures as part of the International Regime, non-parties would be encouraged to join (measures against non-parties) and second, it would promote compliance of the ABS provisions (measures between parties). At the national level, it would also encourage coordination between different Ministries.

An additional advantage of simplified procedures could be to add enough flexibility to take into account the different situations among sectors in ABS and so contribute to the sector-specificity of measures.

Any measure would need to be part of a package of measures, including *supportive measures.*[4] According to Hoffman (2004), in the end it is the effectiveness and also the efficiency of the package, rather than just one single measure, that are important. Therefore, any proposed measure should be integrated into a package of other non-trade measures (information requirements for the databases) and other, supportive measures that could be further developed.

The idea would operate as an incentive for promoting compliance of the ABS provisions.

The use of incentive measures requires first to identify clearly the cause of the problem before introducing it. The cause in this regard might be that the emphasis in provider measures has led to an emphasis in laws controlling access. This in turn would have led to some overly restrictive laws which ultimately reduce the chances for benefit-sharing. This could be considered as a policy failure that needs to be corrected.

Alternatively, one of the most common objectives of the use of incentives is the removal of perverse incentives. In this sense, the existence of protectionist laws might be considered as a perverse incentive towards informal and illegal markets.

The measure may be required to be incorporated into the discussions within the working groups of the CBD on incentive measures.

Challenges for Implementation

Implementation of the measure at the national level might present special difficulties in relation to embedded distinction/discrimination.

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[4] Trade-related environmental measures are usually part of a package of measures that include non-trade measures (such as production/consumption quotas or information requirements) and supportive measures – often also called positive or compliance assistance measures (such as financial and technical support, training and technology transfer). (Hoffman 2004).

In Mexico, during discussions in 2004 on a Draft ABS Law, these difficulties became apparent. The two main arguments that constantly prevented the insertion of simplified procedures that could discriminate between foreigners were: (i) the compatibility of the measure with trade rules (which will be explored in the next section); and (ii) the consequences of the discrimination in relation to a particular provision of the Mexican Constitution.

It is interesting to see that constitutional provision was used as an argument because it shows how national implementation deals with cultural and historical notions which need to be fully understood.

The Mexican Constitution contains a so called Calvo's Clause,[5] which requires foreigners not to call for protection from their own governments when exercising rights and obligations acquired in Mexico, and agree in that extent to be considered Mexican nationals. This is basically a waiver. The reason behind this is a historical one. During the nineteenth century, Mexico faced two major invasions from foreign powers —both of which were justified under the protection of private interests of foreign nationals conducting business in Mexico. It is not clear how this could be infringed upon by introducing simplified procedures that would discriminate between different foreigners but it does show a historical aversion to affecting foreign trade interests.

Moreover, the issue of discrimination is not only relevant in relation to foreigners, but also in terms of providing equal treatment between nationals and foreigners. If the simplified procedures were available only for foreigners then Mexican users could effectively attack and obtain the nullification of the measure, using the right to equal treatment granted in the Constitution.

National circumstances, like those described above, would have an impact both in the design and the implementation of the proposed measure and should, therefore, be further explored.

Trade Concerns: The Limitations

A key synthesis study by the Organization for Economic Cooperation and Development (OECD) concludes that:

> Trade measures can be an appropriate policy measure to use inter alias: (a) when the international community agrees to collectively tackle and manage international trade as a part of the environmental problem, (b) when trade controls are required to make regulatory systems comprehensive in their coverage, (c) to discourage free-riding, which can often be a barrier to effective international cooperation, and (d) to ensure compliance with the MEA (OECD 1999).

The proposed measure could raise trade concerns because it would give special trading advantages to some countries over others. Such a trade-related environmental measure (TREM), might be incompatible with a basic tenet of the world trade system, i.e. the *non-discrimination principle*, contained in the General Agreement on Tariffs and Trade (GATT). This could be either if the measure allows for trade with some countries but not with others in like products (a violation of the most favoured nation clause, Article I), or if it allows for discrimination between like domestic and imported products (a violation of the national treatment clause, Article III).

However, the GATT also contains an article on general exemptions (Article XX) by virtue of which a Party can deviate under certain circumstances from its basics obligations, including the obligation not to discriminate. Measures aimed at protecting the environment can be pursued according to this article, under paragraph b) and g) on protection of human, plant and animal life and health or protection of exhaustible natural resources respectively. There are some conditions that have to be met in order to benefit from the environmental exemption. The measure must be the least restrictive to trade, must be related to the environment, and must not be a disguised restriction on international trade, or, alternatively, it must be applied in a manner which would constitute a means of arbitrary[6] or unjustifiable discrimination[7] between countries where the same conditions prevail.

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[5] Calvo is the name of the proponent of the provision.

It must bear in mind that TREMs are not uncommon and are actually part of many environmental treaties. The issue is framed within the discussion over the relationship between the multilateral environmental agreements (MEAs) and the provisions of the World Trade Organizations (WTO), formerly the GATT. The discussion over this relationship has occupied significant time and resources in several fora but specifically within the Committee of Trade and Environment (CTE) of the WTO.

Within the CTE and before that, the Doha Declaration, the main debate was whether or not it was necessary to amend the WTO provision in order to accommodate environmental concerns.[8] After Doha,[9] the emphasis has been on developing a specific mandate and the relevant definitions[10] needed in order to implement such a mandate.

In discussing the compatibility between the trade provisions contained in MEAs and GATT/WTO rules, the CTE observed that only a small number of MEAs currently in force contain trade provisions.[11] It has argued, therefore, that the dimension of the problem should not be exaggerated.[12] In addition, no disputes have thus far come to the WTO regarding the trade provisions contained in an MEA.

Examples among MEAs of trade measures *amongst parties* include the Basel Convention's ban on the Transboundary Movement of Hazardous Wastes on trade in hazardous wastes, whether for recycling or for final disposal, between essentially OECD and non-OECD Parties to the Convention.[13] Examples of trade measures *against non-parties*[14] include, the trade provisions of the Montreal on Substances that Deplete the Ozone Layer, those of the Basel Convention, and of the Convention on International Trade in Endangered Species, which require parties to apply more restrictive trade provisions against non-parties than to parties.

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[6] WTO panels have accorded special attention to flexibility in the application of the measure concerned. The more rigid and inflexible the application, the higher the likelihood that the measure is regarded as arbitrary and unjustifiable.

[7] A clear definition of trade measures, together with the use of objective, science-based criteria for their use, is also important for ensuring the effectiveness and efficiency of the trade measures in MEAs and avoiding the risk of such measures being regarded as arbitrary and/or unjustifiably discriminatory or a disguised form of protectionism (Hoffman 2004).

[8] Three different positions were clearly identifiable: status quo, to change nothing; soft accommodation, e.g. to develop guidelines; or full accommodation, amend provisions. Eventually the status quo position prevailed.

[9] Paragraph 31 of the Doha Ministerial Declaration launched negotiations, with a view to enhancing the mutual supportiveness of trade and environment and without prejudging their outcome, on "the relationship between WTO rules and specific trade obligations set out in MEAs" (paragraph i).

[10] The reference to "specific trade obligations" (STOs) bin the Doha mandate seems to limit the negotiating mandate to provisions that are *explicitly* provided for and *mandatory* under MEAs.

[11] Often cited is the data that of 200 MEAs currently in force, only 20 contains trade provisions which comes from a study of 1992.

[12] It has been suggested that the analysis should aim at identifying those STOs in MEAs that lack clarity, are inflexible, ineffective and/or highly inefficient and thus might not be compatible with WTO rules.

[13] The ban forms part of Decision III/I entitled *Amendment to the Basel Convention* adopted at the Third Meeting of the Conference of Parties in 1995. It must be ratified by three-fourth of all parties to the Convention prior to its entry into force, and has not yet obtained such a majority.

[14] Although conceptually the Party–non-Party nexus between MEAs and the GATT/WTO is still valid, from a practical point of view it seems to have lost much of its potential as a source of conflict in recent years in the light of the fact that membership of many MEAs has become nearly universal, often being equal to or even greater than the number of WTO member countries (Hoffman 2004).

Despite the increasing number of MEAs that contain TREMs,[15] there has not been, to date, (more than 50 years in GATT-WTO life) a single MEA-WTO dispute (Schwartz 2000). Allegedly, there would be some understandings reached during the discussion of this relationship that have helped to prevent a dispute of this nature.

Opportunities in the MEA-WTO Relationship

Despite these not being binding agreements, it is important to look at some of the understandings that have been forged during the discussion of the interaction MEA-WTO and the use of TREMs. These understandings are similar among the WTO, the OECD and UNCTAD.

Within the WTO it has been understood that:[16]

- The MEAs-WTO relationship should follow the principles of *mutual supportiveness* and *deference.*[17] This would mean that both regimes are not in conflict, can be interpreted in a mutually supported manner and being distinct, and they can hold separate jurisdiction;
- Trade measures agreed to amongst parties to an MEA, even if WTO-inconsistent could be regarded as *lex specialis*[18] under public international law and ought not to give rise to legal problems in the WTO;
- Governments confirmed their agreement —stated in Principle 12 of the Rio Declaration - that environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus;
- Trade measures based on provisions, explicitly agreed that it might be necessary in certain instances to achieve the environmental objectives of an MEA, more particularly when trade is directly linked to the source of the environmental problem;
- When a genuine consensus exists among Parties to an MEA to apply trade measures expressly prescribed, there should be no dispute among them regarding the use of those measures;[19]
- Members of the WTO should attempt to resolve conflicts concerning the use of trade measures for environmental purposes through the dispute settlement mechanisms (DSMs) provided by the MEAs. The improvement of compliance and dispute settlement provisions in MEAs would encourage the settlement of these disputes in the context of the MEAs;

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[15] According to recent UNEP and WTO surveys (UNEP 2001), of the 238 current "International Treaties and Other Agreements in the Field of the Environment" only 38 (13 per cent) contain trade-related measures under which trade provisions have subsequently been adopted by Parties in furtherance of the objectives of the agreements.

[16] See WTO document TN/TE/R/6

[17] See document WT/CTE/M/24

[18] Under the principle of *lex specialis*, if all parties to a treaty conclude a more specialized treaty, the provisions of the latter would prevail over those of the former.

[19] Another important issue is the relationship between the dispute settlement mechanisms (DSM) in MEAs and the WTO. In this regard, there is one growing that for parties of MEAs, any controversy arising from the application of the TREMs should be adjudicated by the DSM established in the MEA. According to Gonzalez-Calatayud and Marceau (2002) no hierarchical organization should exist between the DSM of MEAs and WTO. However, in order to assess conformity with Art XX, a previous assessment of conformity with the MEA must be done.

- With respect to the implementation of MEAs by developing countries, the role and importance of compliance assistance mechanisms (also known as facilitating, supportive or positive measures), in conformity with the principle of common but differentiated responsibility, were stressed; and
- A TREM that discriminates non-Parties is justified as long as it provides the same benefits for that non-Party should it implement equivalent rules than the ones established by the MEA.

Within the OECD (1999) it has been understood that:

- Comprehensive and balanced packages of policy instruments have more chance of addressing all aspects of an environmental problem than reliance on one form of policy instrument;
- A strong scientific basis for policy action increases credibility and acceptance, while at the same time, the absence of full scientific certainty should not prevent action in cases of threats of serious or irreversible damage;
- Flexibility in trade controls can maximize both environmental and economic benefits, and
- Treatment of a non-Party to an MEA like a Party, if such country is in compliance with the provisions of the MEA.

A paper prepared for UNCTAD emphasizes that TREMs in MEAs should be clear, based on scientific environment-related criteria, be sufficiently flexible, be directly linked to the cause of the environmental problem, and be accompanied by adequate and effective supportive measures for developing country Parties (Hoffman 2004).

It should be noted in any case that in the event of a conflict between a MEA and the provisions of the WTO, *sustainable development* must play a major role in connecting both regimes in a mutually supportive way.

This notion was incorporated into the international trade system by the WTO and is the key to construe solutions for any conflictive relation between trade and environment.

Conclusions

The use of simplified procedures for nationals of jurisdictions where user measures have been adopted would encourage non-Parties to: join the international regime; promote compliance of the ABS provisions; encourage coordination between different Ministries; and add enough flexibility to take into account the different situations among sectors in ABS and so contribute to the sector-specificity of measures.

National circumstances have an impact both in the design and the implementation of the proposed measure and should therefore be fully understood.

In relation to the trade concerns the measure might raise, there is an opportunity to explore and acquire experience on the use of TREMs in the international regime on ABS, thanks to the emergence of certain understandings in the MEA-WTO debate and the analysis on compatibility of TREMs with the trade system.

However, it is necessary to explore further the proposed measure with a view to reviewing its clarity, effectiveness and efficiency.

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D. Benefit - Sharing: Benefits-sharing as a goal of the IR

Access to Genetic Resources and Benefit-sharing

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Introduction

One of the three objectives of the Convention on Biological Diversity (CBD) which entered into force in 1993, as set out in its Article 1, is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding". The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which recently entered into force in June 2004, is another comprehensive international agreement which aims at guaranteeing food security through the conservation, exchange and sustainable use of the world's plant genetic resources, as well as the fair use and equitable benefit-sharing, in harmony with CBD.

ABS and CBD

A framework for the implementation of the third objective of the Convention with regard to access to genetic resources is provided in Article 15 (Access to Genetic Resources) of the Convention. In addition, Article 8(j) contains provision to encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

Therefore, Articles 15 and 8 are particularly important in laying the foundation for ABS. Article 15(1) recognizes state sovereignty over natural resources in the context of access to genetic resources. This is very important as it allows states to control access to these resources, allowing for the possibility of profiting from providing access. Under Article 15(4), access to genetic resources is to be on mutually agreed terms subject to prior informed consent. Article 15(7) also provides a framework for the implementation of the third objective of the Convention, namely the fair and equitable sharing of benefits.

Since CBD entered into force, efforts to implement the provisions on ABS have resulted in the development of national ABS legislation, model contracts, and other instruments in various countries. So far, the majority of the attention has focused on developing regimes to control access in provider countries, although there has been some attention paid to developing enforcement measures to ensure that users of genetic resources fulfill their responsibilities.

ABS and FAO

The world faces a major challenge to protect future food supplies and ensure the livelihoods and food security of the next generations. FAO estimates that throughout human history, around 10,000 species have been used as food and feed throughout history. This diversity of use has drastically been reduced, to the point where no more than 120 cultivated species provide around 90% of current food needs. Much of the world's most important genetic material has been preserved by traditional agriculturalists.

As the genetic base of food and feed crops in primary use has narrowed, the remaining plant genetic resources —primary building blocks and progenitors of food varieties and fodder— are essential to enable agricultural production to adjust to climate change, and to maximize the resilience of the food supply in the face of shortages caused by disease, catastrophe, and decreasing agricultural area.

For all of these reasons, FAO has long been attempting to combat the loss of agricultural diversity, while ensuring that this important genetic material remains available to enable constant improvement in food production. It is clear that genetic resources will increase in importance in the future as tools for development of new varieties.

The ITPGRFA represents the answer to that major challenge by defining the special role of agricultural genetic resources. The Treaty is a comprehensive international agreement which aims at guaranteeing food security through the conservation, exchange and sustainable use of the world's plant genetic resources, as well as the fair use and equitable benefit-sharing, in harmony with CBD. It also recognizes the '-Rights.htm" Farmers' Rights to freely access genetic resources, to use and save seeds, under national laws.

The Treaty will implement a Multilateral System of access to a list of 64 (as in Annex I) of the most important food and forage crops essential for food security and interdependence for those countries that ratify the treaty. It includes a funding mechanism that receives shares arising from the commercial utilization of plant genetic resources under the system. The treaty is monitored by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO. The CBD brought genetic resources under jurisdiction of national government, thereby outdating the International Undertaking (IU) which relied on the principle of genetic resources being common heritage of humanity.

Implementation of the Bonn Guidelines

The guidelines were developed in response to growing concerns in many developing countries that the commercial and scientific gains realized from their genetic resources were being reaped only by bioprospectors based in foreign countries. Although voluntary, the Guidelines could offer guidance on the roles and responsibilities of the various parties, and describe each of the steps involved in the process of obtaining access to genetic resources and sharing the benefits.

These could be used to advise governments on how to establish generally accepted norms that set fair and practical conditions for users seeking genetic resources. In return, these users must offer benefits such as profits, royalties, scientific collaboration, or training. The Guidelines could improve the way foreign companies, collectors, researchers and other users gain access to valuable genetic resources in return for sharing the benefits with the countries of origin and with local and indigenous communities. The Guidelines also propose a range of complementary ABS measures that both "provider countries" and "user countries" should consider adopting in order to promote realization of the ABS objectives.

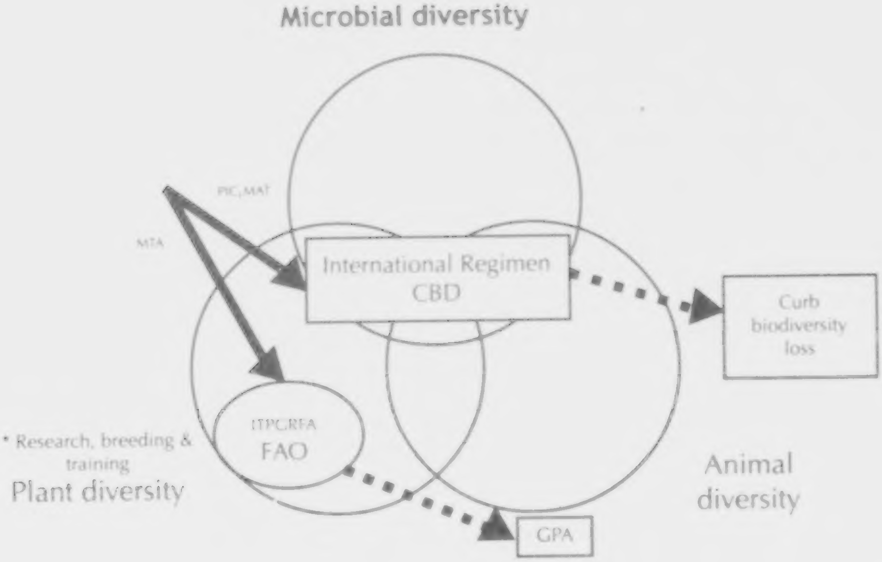

Figure 1. Schematic representation of Access to genetic resources and benefit-sharing (ABS) under CBD and FAO

Negotiating an International Regime on ABS

A major achievement in COP7 was the decision to mandate the Working Group on ABS to negotiate the international regime on access and benefit-sharing and agreement on the terms of reference for such negotiation, including the process, nature, scope and elements for consideration in the elaboration of the regime. The Working Group will be convened twice, and report its progress to COP8 in 2006.

Placed by the WSSD under the aegis of sustainable development, ABS can be considered as a tool for poverty alleviation and environmental sustainability through the monetary and, more importantly, non-monetary benefits that can be gained in exchange for access to potentially valuable resources. The COP7 also agreed on the terms of reference for such negotiation, including the process, nature, scope and elements for consideration in the elaboration of the regime.

A legally binding regime that would not only require the adoption of measures by user and provider countries, promote certification, operationally benefit-sharing, and ensure the international respect of national sovereignty over natural resources, but also address derivatives and include dispute settlement mechanisms. However, mandating the Working Group on ABS to negotiate the regime was one of the few areas of agreement. Ultimately, whatever the outcome of the negotiation on the international regime, at best the latter would be just to set the minimum standards, and thus leave countries the freedom to adopt stricter domestic measures.

Equitable Sharing of Benefits

To some extent, the Bonn Guidelines provide the broad mechanisms to realize this objective. The equitable sharing of benefits should be able to:

- Promote technological innovation;
- Provide incentives for conservation, and

- Reward physical and intellectual contributions of individuals who protected, developed or explored the biological diversity involved.

One of the principal achievements of the Convention is that it provides an international legal framework to foster the establishment of mechanisms to conserve and sustainably use biological diversity. In the case of plant genetic resources, the ITPGRFA is premised on the notion that countries will benefit from germplasm access and exchange through the Multilateral System.

Any number of mechanisms could serve to target benefits to particular individuals, communities or countries. The Convention permits a link between a genetic resource and a claim on economic returns from commercial use of the genetic resource. This is the ultimate in targeting of returns, although there are other types of mechanism that may be appropriate. Several factors influence the design of such mechanisms. One important factor is the transaction costs associated with the targeting of benefits. Thus, the design of benefit- sharing arrangements should take into account the cost-benefit ratio involving the transaction costs associated with the mechanisms for targeting the benefits and the potential profits from the transaction. The cost-benefit ratio is very much likely to differ considerably between transactions geared for pharmaceuticals and those geared for agricultural products. In the case of pharmaceuticals, the potential profits from drug discovery are large, and this may only involve one source of genetic resources. In contrast, agricultural products, e.g. new plant varieties, typically do not generate large profits.

It has also been widely suggested that benefit-sharing could be enhanced through the disclosure of the sources of genetic resources and traditional knowledge in patent applications.

Constraints and Challenges

Today, there are many more countries which have developed measures to address access and benefit-sharing. The number of countries is growing, however, at a relatively slow pace. This is paralleled by the number of bioprospecting activities being carried out, with reports suggesting that the number of multi-national pharmaceutical companies interested in biodiversity prospecting and companies involved in natural products' research is declining. Over-reliance on bioprospecting for pharmaceuticals and drug discovery has, unfortunately, a very strong bearing on the development of ABS measures in many countries; despite the fact that many understand that the flow of potential benefits from pharmaceuticals should not preclude the other uses of genetic resources.

National ABS frameworks only exist in a limited number of countries, but even there many such packages are incomplete. The ABS measures include legislation, strategies, policies, and guidelines. Considerable efforts are needed, particularly through capacity-building projects, to help the developing countries in particular to put in place appropriate national ABS regimes.

In the Malaysian context, the process to develop ABS legislation began in 1994, and five years later in October 1999, the final text of the first draft was adopted. While the above process was taking place at the national level, the States of Sarawak and Sabah had their own processes underway, and these culminated in the enactment of the Sarawak Biodiversity Center Ordinance in 1997, and the Sabah Biodiversity Enactment in 2000. The proactive positions of the States of Sarawak and Sabah are underscored by the fact that some of Malaysia's richest biodiversity is found in these two states. One major constraint in developing a national ABS regime stems from the Federal-State jurisdictional dichotomy over the ownership of land and natural resources, which means that the implementation of an ABS access regime must be endorsed by the States. Other constraints include the contentious and unresolved issues regarding intellectual property rights and traditional knowledge, both of which are currently debated at various international fora.

At the international level, there is a lukewarm reaction from many diversity-rich countries to the Bonn Guidelines, which contrasts with their own push to develop a legally-binding ABS regime.

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Benefit-Sharing as a Goal of the International Regime: Lessons Learned from Genetic Resources Research at Yellowstone National Park

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Genetic resources research at Yellowstone National Park has a long and rich experiential history that may offer some insights for the international community to consider as discussions continue about how an international ABS regime could further the benefit-sharing aims of the CBD. While the first known genetic-resource specimen collection permit was issued at Yellowstone more than 100 years ago, in August 1898, data relating to research activity at Yellowstone since the 1960s may help clarify some of the factual and procedural issues relating to benefit-sharing as a goal for an international ABS regime. However, although the lessons learned from Yellowstone's experience may have some relevance to these issues, it would be premature to suggest that the lessons learned from Yellowstone necessarily reflect any *national* experience in a country as large and diverse as the United States. Nonetheless, the Yellowstone experience may be one of the most instructive and well-documented.[1]

Who is doing research on genetic resources at Yellowstone?

The identity of most of the genetic resources researchers currently working at Yellowstone largely reflects the characteristics of the research community who is interested in the type of unusual genetic resources, found in abundance at Yellowstone, that are of greatest current scientific interest: namely, the thermophilic ('heat-loving') microorganisms being discovered in the thousands of hot springs and related environments protected and preserved at Yellowstone. Whereas this group reflects the largest single concentration of genetic resources scientists currently conducting research at Yellowstone, there are also many other scientists conducting research on other important biological resources found at the park (such as rare or endangered plants and animals). Although Yellowstone hosts a diversity of genetic resources research projects, research projects that have resulted in discoveries with some potential commercial value have been concentrated in the area of thermophilic microorganisms.[2]

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* The views expressed and information presented in this paper have been prepared by the author, and do not necessarily reflect the views or positions of Yellowstone National Park, the US National Park Service, the US Department of the Interior, or any other agency or department of the US Government. The author may be contacted by email at *preston@wfed.org*.

[1] An updated history of Yellowstone's experience that may be of relevance to ongoing ABS discussions will appear in late 2004 in a new book entitled *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (Carrizosa, S., Brush, S.B., Wright, V.D., & McGuire, P.E., eds. (to be published as IUCN Environmental Policy and Law Paper No. 54 (Ch. 8) (Scott, P., 'The United States of America: The National Park Experience', 2004).

[2] Thermophilic ('heat-loving') microorganisms are just one type of 'extremophilic' organisms that thrive in many different types of extreme environments, which have made them of particular interest to science and industry for many years. *See, e.g.*, Madigan, M.T. & Marrs, B.L., 'Extremophiles,' *Scientific American* (April 1997), at pages 82-87; Adams, M.W. & Kelly, R.M., 'Enzymes from Microorganisms in Extreme Environments,' *Chemical & Engineering News* (Dec. 18, 1995), at pages 32-42.

All scientific researchers who want to conduct research projects at Yellowstone must be permitted, and US National Park Service (NPS) regulations authorize the issuance of research and specimen collecting permits only to researchers affiliated with reputable scientific organizations.[3] Permits are granted to qualified researchers from academic and non-academic institutions, for-profit and not-for-profit corporate organizations and firms, and governmental and non-governmental entities from the United States and abroad.

While most researchers have some academic affiliation, many do not. In addition, many academic researchers also have some corporate affiliations or support, while corporate researchers also may have some academic connections. In all cases, it is virtually impossible to categorize any researcher as strictly 'commercial' or 'non-commercial' based solely on institutional affiliation.

Most researchers working on Yellowstone's thermophilic microorganisms could be described as working in 'discovery'-related fields. These include researchers who are interested in the discovery of new types of thermophilic microorganisms, as well as researchers who are interested in the discovery of new information about the genetic characteristics of such microorganisms as well as the potential uses of such genetic information and material.[4]

In addition, most such researchers are conducting research in fields where there is some known utility for the type of thermophilic genetic information and material being discovered at Yellowstone. These include a wide range of fields where there is interest in novel uses of enzymes with some potential industrial application and value. Examples include waste remediation, energy production technologies, paper manufacturing, and food processing.[5]

What is the nature of benefits that can be expected from public research organizations and universities?

The types of monetary and non-monetary benefits described in the Bonn Guidelines[6] can be generated from genetic resources research conducted by public research organizations and universities (especially those with competent technology transfer offices). However, the *value* of both types of benefits is dependant on the quality of the research conducted and the demand for any technological or product development resulting from such research. Legal requirements or constraints, institutional capacities and arrangements, and policy considerations also can affect the types of potential benefits that can be generated.[7]

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[3] *See* 36 CFR 1.6 ('Permits') and 2.5 ('Research specimens').

[4] This type of discovery-related diversity among such researchers is exemplified by the principal researchers involved in discovery of *Thermus aquaticus* and subsequent development of the Polymerase Chain Reaction (PCR): *T. aquaticus* was discovered by Dr. Thomas Brock (an academic researcher from Indiana University) in 1966, while a heat-resistant enzyme ('*Taq* polymerase') was subsequently and independently discovered and isolated from *T. aquaticus* by researchers at the Cetus Corporation (a for-profit research firm) who also recognized the utility of *Taq* polymerase for successful development of PCR.

[5] *The Wall Street Journal* has reported that thermophilic microorganisms from Yellowstone have been used in the development or improvement of the following specific types of industrial processes: improving texture of baked goods; converting milk to cheese; tenderizing meat; improving clarity, flavor and foam in beer brewing; removing oils and grease from fabrics; breaking down wood components in paper production; replacing chemicals in paper bleaching; improving textiles' ability to absorb dyes; and, replacing chemicals in tanning leather. *See* Burton, T., 'Yellowstone's Geysers Spout Valuable Micro-Organisms,' *Wall Street Journal*, Aug. 11, 1997, at page B1.

[6] UN Doc. UNEP/CBD/COP/6/20 (7-19 April 2002) (Decision VI/24 ("Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization").

[7] For example, Yellowstone and other US national parks have not historically imposed 'access' or other specimen-collecting fees on researchers.

Technology transfer and related economic data collected and reported by the Association of University Technology Managers (AUTM) suggest that the valuable research discoveries resulting from university-related research are frequently licensed for further evaluation or development to other organizations and firms.[8] However, because the data reflects discoveries resulting from a wide range of research fields (not simply biological or genetic), it is not possible to extrapolate from published AUTM data the values resulting from biological or genetic research activities only. Nonetheless, there appear to be some observable patterns worth monitoring. These include increasing sums earned from technology licensing activities over time, higher returns for universities with established technology-licensing offices (compared to newly established offices), but relatively few high-value (greater than US$1 million) revenues resulting from any single discovery or invention.

In order for the provider(s) of any genetic resources, used in the successful development of any such discoveries or inventions, to share in such benefits (if any), there must be some legally-binding contractual or other arrangement. For example, terms and conditions providing for the negotiation of a commercial use license *prior to* commercialization of research results are increasingly common in many contractual agreements. However, the AUTM data suggests that any such economic benefits would be based on a negotiated 'percentage of a percentage' (which could increase over time, but which is not likely in any single case to be very high-value). Nonetheless, failure to take *any* action to negotiate equitable and efficient benefit-sharing arrangements with public research organizations and universities effectively guarantees that *no* benefits will be realized.[9]

What are the most important factors determining corporate investments in biodiversity-related research of a commercial nature?

While Yellowstone does not monitor 'corporate investments' in biodiversity-related research that could have some potential commercial value, it has been observed that researchers desire legal certainty and administrative transparency and efficiency with respect to permitting authorizations and the reasonable treatment of any valuable research results (particularly in connection with intellectual property rights). They also are attracted by concentrations of novel genetic resources that are perceived to provide important opportunities for making new discoveries that could be valuable to science as well as to some potentially useful (and therefore valuable) industrial application. Coupled with their interest in the biological resources themselves, firms also have been observed to be willing to increase the value of their research-related investments when it is clear that the investment is supporting sound biodiversity management practices that in turn protect the resources for the future.

Can biodiversity/genetic resources alone be enough to attract foreign direct investment or are other factors that support private sector innovation (e.g., S&T infrastructure, incentives) also necessary? In other words, is biodiversity a necessary but not sufficient condition to attract private sector investment?

While the concept of 'private sector investment' is not germane in the Yellowstone context because of its special position as a premiere national park, the combination of important genetic resources of significant scientific interest coupled with well-established legal and administrative structures have contributed to Yellowstone's ability to attract substantial scientific research activities (particularly in recent years). It should be noted that it is the policy of NPS to encourage scientific research activities in US National Parks (including but not limited to private sector researchers),[10] and this policy is implemented in part through updated research permit guidelines designed to improve the administrative transparency and certainty relating to permitting procedures.[11]

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[8] *See* Association of University Technology Managers, 'AUTM Licensing Survey: FY 2002' (survey summary of technology licensing and related performance for U.S. and Canadian academic and non-profit institutions, and patent management and investment firms) (available online at www.autm.net.). Two-hundred twenty-two (222) U.S. and Canadian universities, teaching hospitals, research institutes, and patent management and investment firms participated in the FY 2002 Survey.

[9] *How* equitable and efficient benefit-sharing arrangements could be structured with public research organizations and universities - *and their downstream licensees* - requires substantial additional data and study.

Although these measures are not intended to attract 'investment' (as that term is used for purposes of this discussion), they are intended to attract qualified researchers to undertake valuable research activities in US national parks. Accordingly, in order to attract and cultivate meaningful and productive 'investment' in biodiversity-related programs, there must be important biological resources that are protected, demand for those resources by qualified research institutions, and the political will to implement and manage pragmatic and effective ABS policies and goals.

What is the probability of research success and time frame for realizing benefits from research on genetic resources used to develop innovative to [sic.] pharmaceutical products?

It is difficult if not impossible to predict with any reasonable degree of certainty the probability of 'research success' (which has been described as a 'random variable'[12]). However, the number of patents that are known to have been granted on inventions resulting from research involving the use of genetic material originally collected from Yellowstone suggests that this type of 'research success' has occurred with some regularity since the 1980s, and continues. For example, there have been more than 40 such patents granted since the early 1980s (the most recent in June 2003). All have involved the use of microorganisms or genetic material isolated from such microorganisms. The commercial success of the patents resulting from the isolation of *Taq* polymerase from *T. aquaticus* and its use in the development of PCR has been widely reported. The economic value of the other patents is not known because NPS has not historically required the reporting of such information.

Likewise, it is difficult if not impossible to predict with any reasonable degree of certainty the 'time frame for realizing benefits.' However, the Yellowstone experience suggests that the 'time frame' may be significantly shorter for developments in fields focusing on the discovery of enzymes and other bioactive molecules than in pharmaceuticals (widely reported to be more than ten years). For example, the Diversa Corporation announced in 2002 that it had developed a new enzyme product ('*Pyrolase 200*') from Yellowstone-related research initiated in the 1990s.

If 'success' is meant to be something less than final product development and marketing, the 'time frame' also can be shorter. For example, benefit-sharing agreements that provide for milestone payments or other research, *process*-related 'success' can generate the economic circumstances required to trigger a negotiated payment obligation sooner than final product development and marketing.

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[10] See, e.g., National Parks Omnibus Management Act of 1998, 16 USC § 5935.

[11] See National Park Service, Research Permit and Reporting System (available online at http://science.nature.nps.gov/research).

[12] See Artuso, A., 1997. *Drugs of Natural Origin: Economic and Policy Aspects of Discovery, Development, and Marketing*, p 121.

What type of biodiversity-based products or markets (e.g. microorganisms, food, low regulatory costs) are likely to yield financial benefits from successful commercial products and processes in the short-term?

There have been many studies that have attempted to document the range of products and markets that can yield monetary benefits from successful biodiversity-related research results.[13] While there is a wide and growing diversity of such products and markets, it would appear that high-value but highly-regulated products and markets (such as pharmaceuticals) do not yield product-related benefits in the short term. The record of discoveries resulting from microorganisms originating from Yellowstone suggests that enzyme and other molecular-related developments can yield benefits earlier. However, *no* benefits are yielded in either the short- or long-term *unless* some benefit-sharing arrangement is in place.

What country-to-country scientific partnerships/models might lead to the successful commercialization of products and resulting benefit-sharing?

All of the research activities that have been undertaken involving the use of genetic resources first collected at Yellowstone, and that yielded research results that could have generated benefits, have involved individual researchers affiliated with some reputable scientific organization (either from the United States or abroad). Yellowstone does not discriminate against non-US research applicants or their affiliated institutions; all applicants are subject to the same regulatory requirements, terms and conditions. However, the record suggests that all active Yellowstone-related genetic resource research activities that have lead to the successful commercialization of products have been developed and conducted at some 'organizational' or 'institutional' level presumably since the successful commercialization of products rarely occurs at 'country-to-country' levels.

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[13] See, ten Kate, K., & Laird, S., 2000. *The Commercial Uses of Biodiversity*. *See also* Bull, A., Ward, A., & Goodfellow, M., 2000. *Search and Discovery Strategies for Biotechnology: the Paradigm Shift*, Microbiology and Molecular Biology Reviews (American Society for Microbiology) (Sept. 2000), p 573-606.

DISCUSSION PAPER

Benefit-sharing as Process

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The "benefit-sharing" aspect of access and benefit-sharing (ABS) is predominantly discussed in terms of sharing *financial* benefits from the commercialization of genetic resources and related traditional knowledge. This monetary approach, based on end-products, is the most obvious and straight forward way to share benefits of research, but is it the most equitable way for all stakeholders?

Given the low probability and lengthy timeframe of commercial profits from "research successes", it could be argued that benefit-sharing based on potential financial payments works best for the institutions that support research (i.e., government, university and corporations) but that are not, themselves, direct participants in the field and laboratory work involved. Those who are "on the ground", conducting and directly participating in research, such as university scientists and members of indigenous and local communities, often have more practical expectations and conceptions of benefits than their sponsoring institutions and governing authorities. University scientists, for example, may be far more concerned about ensuring continuing research funding and funds for graduate students over the next few years than a potential financial payoff a decade or more down the road. Community members may be concerned about gaining employment and training opportunities through the research process, and receiving the results of the research in a timely manner and useful form for local applications.

That benefit-sharing needs to be conceptualised in terms of both monetary and non-monetary benefits over a range of temporal scales is not a new idea, but it does warrant a reminder in any discussion of ABS regimes. Appendix II of the Bonn Guidelines[1] outlines some useful suggestions for monetary and non-monetary benefits beyond simply shared revenues from commercial products. Many of these suggestions reflect the needs and expectations of ground-level stakeholders (i.e., those conducting and participating directly in research).

Lessons from bioprospecting projects and programs that have attempted to incorporate and implement such benefits underscore the complexity involved in doing so, and point to a further need to draw attention to some additional considerations —namely, that some of the benefits themselves have pre-requisites that need to be met before the benefits are useful to the beneficiaries. An example is a university scholarship at a North American university created as an educational opportunity for a student from a developing country, perhaps from a collaborating indigenous community. A pre-requisite to use the scholarship is the ability to speak and write in English, which may disqualify a large number of interested students who are not fluent in English.

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[1] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (COP 6 Decision V1/24).

Addressing these kinds of pre-requisites to benefits also requires an explicit acknowledgement of the interrelatedness between benefit-sharing and such things as relationship-building and capacity-building. For example, in some cases, developing country and community partners have not yet developed or codified their own internal processes (e.g., for giving permission and consent to outsiders), which are necessary to engage in negotiation of mutually agreed terms with outside partners. Providing the assistance to do so is often categorized as "transaction costs" of research and development, which overlooks and degrades the essential role that ABS regimes can play in assisting local institutions and communities to develop self-sufficiency. Within the ICBG program of NIH,[2] for example, developing contractual agreements between developed country universities and companies and developing country partners (in some cases including indigenous groups) has ranged from several months to a couple of years.

At least for communities, the local capacity and processes built during this time are equally if not more important than the resulting contractual arrangements; while the contracts serve the immediate project, the capacity to *develop* contracts, drawing on the templates, processes and negotiation expertise developed, can facilitate future opportunities beyond the immediate project. This is especially important given that, from a community perspective, most research projects are of relatively short duration (i.e., two to five years), so without a blockbuster commercial product, no single project in itself is likely to make a significant socioeconomic impact on the lives of local people.

The concept of "benefits" has evolved from monetary payoffs based on commercial end-products to encompass more of a continuum of possibilities that meet the needs of a diversity of stakeholders. However, the practice of benefit-sharing tends to fall short of these aspirations. It may be helpful to re-conceptualise benefit-sharing as a *process* that includes some real or potential payoffs, but doesn't depend exclusively on them. Like the concept of prior informed consent (PIC), benefit-sharing ought to be envisioned as a process that begins with the relationship-building that may be necessary to develop an equitable research relationship, and extends throughout the research and development process, including reporting back to the research participants whether or not a commercial product is developed.

The concept and practice of benefit-sharing needs to reflect a balance between not only developed and developing country partners from different sectors (university, government, corporate, civil society) but also between the needs of those *directly* conducting and participating in research and their affiliated institutions and organizations.

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[2] International Cooperative Biodiversity Groups (ICBG) Program administrated by the National Institutes of Health (NIH).

DISCUSSION PAPER

Benefit Sharing

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At CBD COP7, some Parties were of the view that there was already access to genetic resources and what was principally needed was an international regime to ensure benefit-sharing. Others expressed the view that the regime must address both access and benefit-sharing. The key point for these discussions is that there is a strong interest amongst many countries to create effective measures to promote the equitable sharing of benefits from the use of genetic resources. This paper will consider some issues and opportunities related to benefit-sharing.

First and foremost, to ensure benefit-sharing it is just enough to create an efficient and fair legal framework at the national and international level consistent with the objectives of the CBD and Article 15. At both the national and international level, sustainable development measures to conserve genetic resources in-situ, public/private sector investments in biodiversity-based innovation, market-based incentives and international S&T cooperation will also be essential for the development of efficient international markets for genetic resources.

Efficient and Fair ABS Laws

ABS law is a marketplace framework law. Like competition or intellectual property law it is desirable to design laws that promote economic efficiency while at the same time ensuring fairness as it relates to legal procedures ensuring transparency and due process, consideration of the public interest and the rights of various stakeholders, as well as addressing broader social equity and rights issues. These various objectives need to be achieved while at the same time the regulatory burden of regulations and the transactions costs of negotiating mutually-agreed terms are minimized. In effect, countries will not only compete for foreign direct investment based on the abundance and uniqueness of their genetic resources but also based on how efficient and fair their ABS laws are. This is true beacuse there are many biodiversity-based investment opportunities and relatively few dollars chasing biodiversity-based research at this stage in the development of genetic resource markets.

Sustainable Development Measures

It is reasonable to assume that society/markets will place a higher value on genetic resources in the future. However, in many current instances, benefit-sharing from the commercial use of genetic resources is unlikely to have a significant impact on curtailing the loss of biodiversity/genetic resources. It will still be more profitable in the short term to cut down forests for timber products. Thus, government measures to create protected areas or to integrate the preservation of genetic resources

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[1] The views expressed are solely those of the author.

(i.e. unique ecosystems and species) into resource management will be important to ensure long term benefit-sharing from genetic resources. In this way, ABS policy may be linked to conservation measures. On the one hand, financial contributions from developed countries may be necessary to establish protected areas in developing countries. On the other hand, commitments to national conservation by developing countries could theoretically be a condition of developed countries in the negotiation of an international regime.

Investments in Biodiversity-based Innovation

The WSSD Plan of Action identified the need for the provision of new and additional financial and technical resources to developing countries in order to achieve a significant reduction in the current rate of loss of biological diversity by 2010. In support of this commitment, developed countries could make commitments for biotechnology S&T investments in developing countries in order to increase the level of basic and applied biodiversity-based research. An interesting model for such investments is evolving in some ASEAN countries. An example is BioIsland in Indonesia which is an integrated area for research, development and production of biotech-based industry. Besides access to genetic resources, these biotech parks may provide tax, custom and immigration policies to encourage investments. Another model is Australia where public policy is supporting measures (e.g. S&T infrastructure, bio-informatics, taxonomy/genomics) which will make biodiversity-based research more profitable by increasing the probability of research and commercial success. Clearly, public and private sector investments and partnerships between developed and developing countries are a potential benefit-sharing model that can achieve both biodiversity and development objectives.

Market-based Incentives

Intellectual property rights, preferential tax treatment immigration and customs procedures are a range of market-based incentives that can complement a national biodiversity/biotech/genomic innovation strategy.

International S&T Cooperation

The Human Genome Project is a good example of international S&T cooperation that biodiversity-based research can build upon. It is now common for national genomics institutes to fund non-human genomics research. Currently, only approximately 10% of the planet's species are known. It is apparent that an international taxonomic/genomic effort is needed at a level many magnitudes of the scientific effort and financial support than mapping the human genome. Funding of the Global Taxonomy Initiative at the levels needed to help achieve the WSSD 2010 targets would in themself lead to a significant scientific effort/benefit-sharing in developing countries.

Annexes

Agenda

Objective:

The objective of this Experts Workshop is to facilitate an open discussion on aspects of the international ABS regime and to prepare a report of the workshop that will be transmitted to the CBD Secretariat for distribution as an information document for the 3rd Meeting of the Ad hoc Open-ended Working Group on ABS to be held in February 2005.

Day 1: Sunday, October 24

Arrival of Participants

17:00 - 20:00	**Registration** Hotel Reception
19:00 - 21:00	**Welcome Reception**

Day 2: Monday, October 25

8:00 - 9:00 **Registration**

Opening Remarks:

9:00 - 9:30 Representative of the Minister of Environment and Natural Resources (Semarnat)

9:30 -10:00 **Common goals:** Mexico & Canada co-chairs

- ☐ Timothy Hodges, Associate Director, Biodiversity Convention Office, Environment Canada
- ☐ Jorge Soberón Mainero, Executive Secretary, Conabio

Day 2 (continues)

Overall Vision

I. **Identification of Outstanding ABS Issues**

10:00 - 10:30	**Level of national implementation** (Lessons learned from implementing the Bonn Guidelines)

- ☐ Valérie Normand

10:30 - 10:45 **Coffee break**

10:45 - 12:00 **National access laws (challenges), continuing monitoring and enforcement issues**

- Paz Benavidez
- Geoff Burton
- Santiago Carrizosa
- Robert Lettington

12:00 - 13:00 **Access to genetic resources and intellectual property rights: what is biopiracy?**

- Graham Dutfield

13:00 - 14:30 **Lunch**

II. Vision and Nature of an International Regime: Goals, Challenges, Gaps and Role of CBD and Other Bodies

14:30 - 16:00 **Vision and Nature of an International Regime**

- François Pythoud
- Tomme Young
- Joshua Rosenthal

16:00 - 16:15 **Coffee break**

16:15 - 18:00 **Vision and Nature of an International Regime (cont.)**

- Stephen Smith
- Peter Einarsson
- Robert Lettington

19:00 - 21:00 **Dinner**

Day 3: Tuesday, October 26

III. Specific issues for consideration in the elaboration of the IR

Intellectual Property Issues (The relevance of existing IPR issues for the development of the IR, How should IPRs be addressed in an international regime?)

9:00 - 11:00 **Interface with Existing IP System & Limits and Opportunities for Existing IP Rights**

- Martin Girsberger
- Kim Connolly-Stone

11:00 - 11:15 **Coffee Break**

11:15 - 12:00 **Interface with Existing IP System & Limits and Opportunities for Existing IP Rights (cont.)**

- William Kingston
- Ruth Okediji

12:00 - 13:00 **Limits to rights over genetic resources, the issue of derivatives. Defining the line between tangible and intangible property rights.**

- Fernando Casas

13:00 - 14:30 **Lunch**

14:30 - 16:00 **New Forms of Sui Generis Protection relevant for the IR (GR and/or TK)**

- Jock Langford
- Graham Dutfield

16:00 - 16:15 **Coffee Break**

16:15 - 17:45 **Indigenous peoples: Community-level PIC for accessing TK and genetic resources, feasibility and good practices**

- Brendan Tobin
- Peigi Wilson
- Paul Kuruk

17:45 - 18:45 **Measures to ensure compliance with CBD and access legislation. Stakeholders, Scientists as users and providers including, Codes of conduct/awareness**

- Kelly Bannister
- Maureen Wolfson
- Joshua Rosenthal

Evening **Dinner**

Day 4: Wednesday, October 27

IV. Instruments/tools/measures which could assist in achieving the International Regime including Mechanisms for Monitoring and/or Verification

Certification systems

9:00 - 11:15 **Product and process certification including certificate of legal provenance/ source/origin**

❐ José Carlos Fernández

❐ Brendan Tobin

❐ Leonard Hirsch

11:15 - 11:30 **Coffee Break**

11:30 - 13:00 **Company conduct, standards and certification**

❐ George Greene

❐ Lene Lange

13:00 - 14:30 **Lunch**

Measures and Compliance mechanisms for key actors (the proposed + any other)

14:30 - 16:00 **Government user measures - incentives for compliance**

❐ Birthe Ivars

❐ Brendan Tobin

❐ Christian López-Silva

16:00 - 16:15 **Coffee Break**

Benefit Sharing

16:15 - 17:45 **Benefit sharing as a goal of the IR (opportunities, kinds of benefits, successful experiences and why, lessons learned, transaction costs, limits to benefit sharing)**

❐ Mohamad bin Osman

❐ Preston Scott

❐ Geoff Burton

17:45 - 18:15 **General conclusions / remarks on the workshop:** Co-chairs

❐ Timothy Hodges, Associate Director, Biodiversity Convention Office, Environment Canada

❐ Jorge Soberón Mainero, Executive Secretary, CONABIO

Evening **Dinner**

About the Panelists

Kelly Bannister is a research associate with the POLIS Project on Ecological Governance and an assistant professor at the School of Environmental Studies, University of Victoria (Canada). She holds a post-doctoral fellowship from the Social Sciences and Humanities Research Council of Canada. She has B.Sc. and M.Sc. degrees in Microbiology/Biochemistry and a Ph.D. in Ethnobotany/Medicinal Plant Chemistry. Her main research interests are in ethics and Indigenous intellectual property rights in research involving biodiversity and traditional knowledge. She is actively involved in both ethnobotanical field research and policy analysis, and works with several First Nations and treaty groups in British Columbia. She is particularly interested in institutional policy development for collaborative research between universities and Aboriginal communities. Her current research explores ethics of community-based research and community protocols as a tool for facilitating equitable research practices. She has authored several journal articles, book chapters and reports and given many presentations on ethical and legal issues in ethnobotanical research.

Paz J. Benavidez II is a lawyer specializing in environment and natural resource issues, and received her Bachelor of Laws from the University of the Philippines in 1995. Atty. Benavidez is a legal research consultant of the Committee on Ecology, House of Representatives, Republic of the Philippines under the United Nations Development Program (UNDP)-funded ENR Framework Development and Implementation Project and the managing partner of Kho Agsaoay Benavidez & Matammu Law Offices. Her firm has been engaged to draft the proposed *Guidelines on Bioprospecting Activities in the Philippines* of the Department of Environment and Natural Resources (DENR). She was commissioned by the University of California Genetic Resources Conservation Program to prepare a chapter on Philippine ABS regulations as part of a book on ABS which will be published soon. She was a legal counsel of the DENR for two years focusing mainly on access to biological and genetic resources and protected area management. She actively participated in the formulation of the implementing rules and regulations of Philippine Executive Order No. 247 and served as one of the legal counsels of the Technical Secretariat of the Inter-agency Committee on Biological and Genetic Resources (IACBGR).

Mohamad bin Osman is an Associate Professor with the School of Environmental and Natural Resources Sciences in the Faculty of Science and Technology at the Universiti Kebangsaan Malaysia (UKM). By discipline, Dr. Mohamad is a plant breeder and a geneticist, and holds a B.Sc. in Agricultural Genetics and M.Sc. in Genetics from the University of California, Davis, and a Ph.D. in Plant Breeding and Genetics from the University of Wisconsin, Madison. He was involved in agricultural research for 18 years with the Malaysian Agricultural Research Development Institute (MARDI), and had served in various positions in the Institute: as Head of MARDI Research Station in Alor Setar (1979-81), Deputy Director of Rice Research Division (1988-90), Director of Fruits Research Division, and also as Deputy Director of Basic Research Division. In 1995, he joined Universiti Kebangsaan Malaysia (UKM), and is currently the Coordinator for the one-year intensive M. Sc. Program in the Management of Plant Genetic Resources.

In October 2001, he was elected the Co-Chairman of The Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, which came up with the first draft of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

Geoff Burton is Australia's National Competent Authority on Access and Benefit-sharing (ABS) under the Convention on Biological Diversity (CBD). He is the Director of Genetic Resources Management Policy, within the Australian Government's Department of the Environment and Heritage, and Australia's lead negotiator on ABS issues. In 2001 he led the Australian Delegation to the Convention on Biological Diversity meeting that developed the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization and played a significant role in their later adoption by the Convention in April 2002. In 2003 and 2004, he was Australia's lead negotiator in negotiations on Terms of Reference for the development of an international ABS regime. In March 2004, he Co-chaired the APEC Workshop on Trade and the Sustainable Use of Biodiversity focused on the utilization of genetic resources. Within Australia, he was instrumental in the development of national policy on the management of Australia's genetic resources and played a key role in the intergovernmental agreement between all nine Australian governments to implement the Bonn Guidelines. He is also responsible for the development of the federal legislation to manage genetic resources in federally managed areas.

A history graduate of the University of Western Australia, Mr. Burton has had a diverse career ranging from governance reform in China and countries in transition, environment and heritage conservation and management, aircraft accident investigation and law enforcement oversight to public administration reform and accountability.

Santiago Carrizosa is a research ecologist with the Genetic Resources Conservation Program (GRCP) at the University of California (USA). Dr. Carrizosa holds a B.Sc. in Biology from the Universidad de los Andes (Colombia) and received an M.Sc. and Ph.D. in Renewable Natural Resources from the University of Arizona (USA). Dr. Carrizosa's research interests are on the relationships among the Convention on Biological Diversity, national laws and policies that regulate access to genetic resources, and the exchange of genetic resources between countries. His interests extend to the impact of these international and national laws on local biodiversity conservation and sustainable use initiatives. Dr. Carrizosa has written extensively on a wide variety of issues that include biodiversity conservation and sustainable use strategies in Colombia, bioprospecting models in Chile and Argentina, and biodiversity monitoring and evaluation indicators. In 2000, he also published a book titled *Bioprospecting and Access to Genetic Resources* that, among other issues, analyses the pros and cons of the Andean Pact Decision 391 and examines bioprospecting models implemented in the region. In late 2004, Dr. Carrizosa will launch a second book entitled, *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity,* which provides a comparative analysis about the status of access and benefit-sharing policies in all the Pacific Rim Countries that have signed the Convention on Biological Diversity.

Fernando Casas-Castañeda holds a B.Sc. in Administration and Economics as well as a M.A. in Environmental Economics from the University of Nebraska. He also has doctoral studies in development and the environment from the same University. From 1979 to 1990, and again since 1998, he has served as a professor of the Interdisciplinary Center for Regional Studies (CIDER) of the University of Los Andes in Bogotá, Colombia. In addition to his teaching responsibilities, he coordinated the Program for Environment and Development Studies and participated in numerous research and consulting projects carried out by the CIDER in various regions of Colombia and in the countries that belong to the Andean Pact. For the last 15 years, he has acted on behalf of the Colombian government as a negotiator for various specific processes, including the design and formulation of an Andean Group Decision on the Regulation of Access to Genetic Resources and the Biodiversity Regional Strategy, as well as all meetings of the Conference of the Parties to the Convention on Biological Diversity (CBD). Since 1998, he has been a professor at the graduate program in Integrated Environment Management of the civil engineering department of the Universidad de Los Andes and the doctoral program at the Smithsonian Tropical Institute and McGill University in Panama. Lately he has been part of the negotiating team in the Free Trade Agreement between Colombia and the United States and the meetings of the Ad hoc Working Group on Access and Benefit-sharing of the CBD. Since 2001, he holds office as the senior advisor for international affairs of the General Director of the Instituto Alexander von Humboldt.

Kim Connolly-Stone is currently the team leader and a senior advisor of the Intellectual Property Policy Group at the Ministry of Economic Development, New Zealand. In addition to taking an overview of the Intellectual Property Group's work, her specialist areas are copyright and the development of domestic policy on the intellectual property/traditional knowledge interface. She is also responsible for advising the Government on the intellectual property aspects of the Wai 262 – Flora and Fauna - Treaty of Waitangi claim.

Ms. Connolly-Stone represents New Zealand at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. She is also responsible for providing advice on issues concerning intellectual property, traditional knowledge and genetic resources as they arise in the TRIPS Council and the CBD. Relatively new to the CBD area, her interest in CBD and ABS issues was fostered during a short sabbatical to the Biodiversity Convention Office of Environment Canada in 2003.

Graham Dutfield is Herchel Smith Senior Research Fellow at Queen Mary Intellectual Property Research Institute, Queen Mary University of London. He was formerly Academic Director of the UNCTAD-ICTSD Capacity-building Project on Intellectual Property Rights and Development. His current research interests include the history of patent law and the life science industries; biotechnology, genomics and the patent system; plant variety protection; the politics of intellectual property; intellectual property and genetic resources, traditional knowledge and folklore. His books include: *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (2004); *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (2003); and *Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties* (2000).

He has served as consultant or commissioned report author for the following organizations since 1998: Brazilian Foreign Ministry; Commonwealth Secretariat; UK Department for International Development; European Commission; German Ministry of the Environment; International Institute for Environment and Development; IUCN; Scidev.net; Quaker United Nations Office; Rockefeller Foundation; Royal Institute for International Affairs; UNDP; UNEP; WIPO; WHO; and WWF International. He has a DPhil from the University of Oxford.

Peter Einarsson is a part-time farmer and a consultant in the fields of sustainable agriculture, agrobiodiversity, and agricultural biotechnology. Working mainly for Swedish and international NGOs, he has also done work for government agencies. Present contracts include GRAIN (an international NGO), SwedBio (a Swedish government agency) and Ekologiska Lantbrukarna (a Swedish farmers' organization).

Present focus areas under those contracts include WTO agreements (agriculture and TRIPS in particular), WIPO (genetic resources, traditional knowledge and patent harmonization), EU agricultural policies, the CBD-ABS process, and the FAO International Treaty on PGRFA. Some of his recent publications include *Fair and Equitable: Sharing the Benefits from the Use of Genetic Resources and Traditional Knowledge* (with Marie Byström and Gunnel Nycander); *Agricultural Trade Policy as if Food Security and Ecological Sustainability Mattered*; and, *TRIPS: Consequences for Developing Countries. Implications for Swedish Development Cooperation* (with Marie Byström).

Martin Girsberger is Co-Head of Legal Services, Patent and Design Law, Swiss Federal Institute of Intellectual Property. He is Attorney at Law (Berne bar association) and has a Dr. Jur. degree from the University of Berne (Switzerland) and a Master of Law (LL.M.) degree from the Duke University School of Law (USA). He is head of the Swiss delegation to the Intergovernmental Committee (IGC) of WIPO, member of the Swiss delegation to the TRIPS Council, various CBD-fora, and WIPO's Working Group on the PCT-Reform, and advisor of the European Region in FAO's negotiations on the standard

MTA. He co-drafted the Swiss proposals to amend WIPO's PCT Regulations concerning the declaration of the source of genetic resources and traditional knowledge in patent applications. In 1999 and 2001, he was Co-Chair of the CBD's Expert Panel on Access and Benefit-sharing. He wrote several publications in the area of access and benefit sharing, traditional knowledge, Farmers' Rights, and intellectual property, most recently *Transparency Measures Under Patent Law Regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit-sharing* in the Journal of World Intellectual Property (Vol. 7 No. 4, July 2004, pp. 451-489).

George Greene leads Stratos' work on corporate sustainability and CSR. He has been working with the Mining Association of Canada advising on the implementation of the industry-wide *Toward Sustainable Mining Initiative*, including an environmental and social performance measurement and a verification and reporting scheme for industry. He is involved in a similar sustainability initiative with the Forest Products Association of Canada. He works with the executive committees and senior managers of oil and gas utilities, forest products and mining companies on corporate responsibility strategies and on the implementation of management systems to address social and environmental issues.

Mr. Greene was a member of the ABS Expert Panel in 2002 and was the lead negotiator of the Bonn Guidelines on Access and Benefit-sharing for Canada. He co-drafted the international Capacity Building Framework for Biosafety Protocol, which was adopted at the first Meeting of the Parties for the Cartagena Protocol. Currently, he is leading a project, funded by the Swiss Secretariat of State for Economic Affairs, to develop and pilot test an international set of best practice standards and a management system to enable companies and research organizations to access genetic resources through responsible negotiation and contractual arrangements with governments and local and indigenous communities which own these resources used in biotechnology.

Birthe Ivars is Senior Adviser in the Royal Norwegian Ministry of Environment. She is a lawyer specialising in international environmental law. She is the National Focal Point in Norway on Access and Benefit-sharing and Head of the Norwegian delegation to meetings in the Ad hoc Open-ended Working Group on Access and Benefit-sharing. Birthe Ivars chaired the sub-working group developing draft Bonn Guidelines during the first meeting of the ABS Working Group in Bonn, in 2001. She is a member of the Norwegian Genetic Resources Council as well as the Nordic Genetic Resources Council.

William Kingston teaches innovation in Trinity College, Dublin, and is also Visiting Professor at the School of Public Policy of George Mason University, Virginia. His books include *Innovation: the Creative Impulse in Human Progress* (New Edition, 2003); and *The Political Economy of Innovation, and Innovation, Creativity and Law*. He has also directed two major studies for the European Commission, published by them under the title of *Direct Protection of Innovation and Enforcing Small Firms' Patent Rights*. His main research interest is the economics and history of property rights.

Lene Lange is adjunct professor at the Danish Agricultural University and Science Director, Molecular Biotechnology at one of the largest biotech firms in Denmark: Novozymes A/S. Her professional career includes experience across all three major research sectors: 6 years employment at the above-mentioned university; 8 years at research institutes (under the auspices of the Ministry of Foreign Affairs); and the last 17 years with private industry. She also sits on, or chairs, the boards of several national and international commissions. Between 1972 and 2004, she has contributed to over 100 scientific publications. Her current research focuses on the discovery of novel fungal proteins through molecular studies of the interaction between fungi and their host substrate.

Her international experience is extensive: Global spokesperson for Novozymes on Bioethics and Biodiversity (1995-present); CGIAR review missions to Vietnam, Cambodia, India and Nepal; Danida Biodiversity review mission to five Central and South American countries; Danced/Danida Review missions to Southern Africa (1999 and 2003) and South East Asia (2001); numerous

Danida and FAO missions in Africa, Asia and South America; visiting scientist at the University of Michigan, University of California-Davis, and University of Georgia, Athens; research strategy for IRRI, Philippines (1995-2001); and Board member for CIMMYT (2002-present).

Jock Robert Langford is currently the Senior Policy Advisor for Intellectual Property Rights at the Biodiversity Convention Office, Environment Canada. His primary areas of responsibility are the protection of traditional knowledge (Article 8(j)) and access and benefit-sharing from the utilization of genetic resources (Article 15), as they relate to ongoing international negotiations and domestic implementation of the UN Convention on Biological Diversity (CBD).

During the last decade, he has participated on Canadian government delegations' meetings of the Convention on Biological Diversity (CBD) and the World Intellectual Property Organization (WIPO) related to intellectual property rights, genetic resources and traditional knowledge. He coordinated and participated in the Canadian portion of the WIPO Fact-finding Mission on traditional knowledge in 1998. More recently, Mr. Langford was the senior federal government negotiator during the drafting of the CBD Bonn Guidelines on Access and Benefit-sharing from the Utilization of Genetic Resources and actively participated in CBD meetings leading to the CBD COP7 decision to negotiate an international regime. He also led the Canadian negotiating team on *sui generis* regimes at the most recent CBD Working Group on Article 8(j) meeting.

Mr. Langford has a B.Sc. (biology) from the University of Guelph and a B.Sc. (Agr.) in Agricultural Economics from the Ontario Agricultural College.

Robert Lewis-Lettington is Deputy Director and head of the agriculture program of the Southern Environmental and Agricultural Policy Research Institute (SEAPRI), the legal and policy division of the International Centre of Insect Physiology and Ecology (ICIPE). While at ICIPE, Robert has undertaken a wide range of consultancy activities in Africa and Latin America, including work for several UN organizations, governments, NGOs and communities.

He is also a consultant legal specialist in the Genetic Resources Policy Initiative (GRPI) of the International Plant Genetic Resources Institute (IPGRI). He has also worked on intellectual property and biodiversity issues for the African Centre for Technology Studies (ACTS) and on a range of conservation related activities, including research into traditional knowledge in the Kalahari Desert (with Conservation International's Okavango Program).

He holds a Juris Doctor degree in law and a Master of Arts degree in Art History. His primary areas of research interest and professional activity are genetic resources law and policy and the interaction of customary and modern legal systems in the context of rural development. He also has significant experience in intellectual property related issues, including traditional knowledge protection, access to essential medicines and institutional policy development.

Christian López-Silva is a lawyer who has worked as legal advisor in the environmental sector of the Mexican government on biotechnology regulation - his area of expertise. He has worked for the Ministry of Environment and the National Commission for Biodiversity (CONABIO), which involved collaborating with the Interministerial Commission on Biosafety. He has advised in the negotiation of scientific and bioprospecting agreements between Mexican and foreign institutions and has been involved in the discussions and analysis on regulation of access and benefit sharing, traditional knowledge, intellectual property rights, assisted reproduction techniques and biosafety. He led the legal analysis of the group of experts who wrote the Mexican chapter of a major publication on the state of ABS in the Pacific Rim Countries. He holds a Masters in biotechnological law and ethics and is currently in the United Kingdom pursuing doctoral research in the Sheffield Institute of Biotechnological Law and Ethics, at the University of Sheffield. He is currently legal consultant for Conabio on legal and policy issues relating to biotechnological applications.

Valérie Normand is the programme officer responsible for the programme of work on access to genetic resources and benefit-sharing at the Secretariat of the Convention on Biological Diversity (SCBD). A lawyer by training, she has a "Diplôme d'Etudes Approfondies" (D.E.A.) in public international law from the Université de Paris I (Panthéon-Sorbonne). Prior to joining the SCBD in Montreal in 2000, she worked on trade and environment issues, first for the Organisation for Economic Cooperation and Development (OECD) in Paris, from 1994 to 1997, and then on the development aspects of trade and environment issues with the United Nations Conference on Trade and Development (UNCTAD) in Geneva, from 1997 to 2000.

Ruth L. Okediji is the William L. Prosser Professor of Law at the University of Minnesota Law School, where she teaches contracts and a number of courses on intellectual property law. She is an expert on the law and policy of the international intellectual property system. Her work focuses on the negotiation of substantive intellectual property norms in the multilateral environment specifically as they affect developing countries. Professor Okediji has written, lectured, and published extensively in the area of intellectual property and development. Her research and lecture titled *Making Room at the Table: The Protection of Indigenous Knowledge at the Intersection of International Law, Human Rights and Intellectual Property Rights*, has been cited numerous times as a leading work on the interface between intellectual property and traditional knowledge protection. Professor Okediji is also well known for her seminal article on the challenges of the IP system for cultural communities published in 1995. She has served as a consultant with various international organizations, including the United Nations Development Program's flagship project on Innovation, Culture, Biogenetic Resources, and Traditional Knowledge, and the United Nations Conference on Trade and Development Capacity Building Project on Intellectual Property Rights and Sustainable Development.

François Pythoud is a plant biologist by training and holds a PhD in natural sciences. He has worked for the Swiss Agency for Environment, Forests and Landscape on biotechnology and biosafety related issues since 1990. He is the Swiss CBD National Focal Point for ABS. As Head of the Swiss delegation to the Working Group on Access and Benefit-sharing (ABS), he was closely involved in the development and adoption of the Bonn Guidelines on ABS. In 2004, he co-chaired the contact group on ABS during COP 7. At a national level, he is responsible for ensuring the implementation of the Bonn guidelines by the different Swiss stakeholders.

Preston T. Scott is a founder and current Executive Director of the World Foundation for Environment and Development (WFED), which is an independent non-profit organization based in Washington, DC, that was established in 1992 to promote international cooperation and conflict resolution initiatives in the field of environment and development. Mr. Scott's recent work has focused on specialized institutional arrangements relevant to biodiversity conservation initiatives, with special emphasis on access and benefit-sharing issues involving national parks and other protected areas around the world. In this capacity, Mr. Scott has served as a consultant and advisor to several national institutions and organizations including the US National Park Service, the Russian Center for Ecological Research and BioResources Development, and the National Biodiversity Centre of the Kingdom of Bhutan. He has conducted training workshops on negotiating biodiversity access and benefit-sharing agreements in more than 15 countries and over five continents.

Dr. Stephen Smith is a Research Fellow and Germplasm Security Coordinator at Pioneer Hi-Bred International. Dr. Smith has B.Sc. in Plant Sciences from the University of London, and a M.Sc. in the Conservation and Utilisation of Plant Genetic Resources and a Ph.D. in the Taxonomy and Evolution of Maize from the University of Birmingham. He conducted post-doctorate research at North Carolina State University in Raleigh on genetic diversity in maize and teosinte.

Dr. Smith co-chairs the Pioneer/DuPont Genetic Resources Issues Team. The team's major accomplishments include providing support that led to the US signing the FAO International Treaty, gaining $1 million support from Pioneer/DuPont for the Global Crop Diversity Trust, obtaining an annual increase of approximately $20 million in Congressional budgetary support for the US National Plant Germplasm System, and providing advice to the International Seed Federation, the American Seed Trade Association, and the U.S.D.A. for the development of Material Transfer Agreements for the International Treaty. Dr. Smith serves on intellectual property committees of the American Seed Trade Association (ASTA), the National Council of Commercial Plant Breeders (NCCPB), the International Seed Federation (ISF), and CropLife International. He is a Board member of the International Plant Genetic Resources Institute. Dr. Smith is a member of the access and benefit-sharing task force within the International Chamber of Commerce.

Brendan Tobin holds dual Peruvian and Irish nationality. A barrister by profession he has worked for many years on ABS issues. This work has included providing legal advice on negotiation of bioprospecting agreements, the development of regional and national ABS law and policy on ABS, and provision of pro bono advice on natural resource rights to indigenous and local communities. He was a member of the First Panel of Experts on ABS, and attended the COP and other CBD related events as a member of the Peruvian national delegation, in which capacity he co-chaired the re-negotiation of the Bonn Guidelines during COP VI in The Hague. Since 2003, he has been a research fellow at the Institute of Advanced Studies of the United Nations University, where he is Coordinator of the Biodiplomacy Initiative, a research program covering ABS, TK, biosafety and bioethics related issues.

Peigi Wilson is the Director of Environmental Stewardship for the Assembly of First Nations. She is a lawyer specializing in environmental issues, particularly as they impact on indigenous people. She received her law degree from the University of Victoria, B.C., Canada and has a double honors degree in history and political science from the University of Western Ontario in London, Canada. She has worked for the Canadian federal government departments of Indian and Northern Affairs and Environment Canada. She has also worked for the United Nations Environment Programme in Nairobi, Kenya, where she focused on the protection of international water bodies and environment and trade. She lives in Ottawa, Canada and is of mixed heritage - Cree and English.

Maureen Wolfson is Director of Research Services at the South African National Biodiversity Institute (SANBI), where she has been responsible for preparing SANBI policy on Access to Genetic Resources and Benefit-sharing. She has also been involved in the negotiation of a number of NBI projects such as the Millennium Seedbank project, the DNA Bank, and the Anti-Malaria project, to ensure that South Africa's national sovereignty over indigenous resources is not infringed upon, and that proper provision is made for adequate benefit-sharing with relevant stakeholders.

She represented the NBI in a two year DIFID-funded project with participants from botanical gardens from 15 different countries to develop Common Policy Guidelines for Botanic Gardens on Access to Plant Genetic Resources and Model Material Transfer and Acquisition Agreements.

She has been part of the official South African delegation at meetings of the Expert Panel on Access and Benefit-sharing to draw up the ABS Guidelines subsequently accepted by the ad hoc Working Group as the basis for the Bonn Guidelines, as well as representing her country at the Open Ended Workshop in Montreal which drew up the Action Plan for Capacity Building for Access and Benefit-sharing to be presented at COP-7. She is a member of the National Plant Genetic Resources Committee and was instrumental in developing the South African position in the negotiations to develop the International Treaty on Plant Genetic Resources for Food and Agriculture.

Tomme Rosanne Young is currently Senior Legal Officer at IUCN's Environmental Law Centre in Bonn, Germany. A graduate of Hastings College of Law (1981), and the University of Southern California (1978), she is a recognized international expert in environmental law and policy, focusing on the implementation of conservation and other policy objectives and the development of commercial/environmental relationships. She has worked on ABS issues since 1993.

As advisor on environmental, conservation, natural resource, sectoral, and sustainable development law, she has advised the governments of over 20 countries in Europe, Africa, Asia, Oceania and the Americas. In commercial and environmental law practice, she developed incentive legislation and programmes; represented multinational corporations in commercial issues; negotiated and litigated compensation for harm to biodiversity; developed market regulatory systems in intangible and controlled commodities, and negotiated commercial contracts for real and personal property, investment instruments, intellectual property, transferable rights, and controlled substances. In US practice, she specialized in the creation, financing and operation of commercial entities, including the protection of small investors and contracting parties in contracts with corporations, multinationals and governments.

Workshop Participants

Participants

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